**DELEGATION OF OPERATIONAL RESPONSIBILITIES BETWEEN SESLHD AND THE COORDINATING PRINCIPAL INVESTIGATOR FOR**

**Clinical Trial (CT) Approval (CTA) [previously called exemption (CTX)] and Notification (CTN).**

Therapeutic Goods Act 1989, requires [sponsors](https://www.tga.gov.au/role-sponsor) to apply for the TGA's **approval** to supply [unapproved therapeutic goods](https://www.tga.gov.au/accessing-unapproved-products) in Australia via a clinical trial despite the therapeutic goods not being entered in the [Australian Register of Therapeutic Goods (ARTG)](https://www.tga.gov.au/australian-register-therapeutic-goods). The scheme's previous name of CTX underscored the **exemption** given by the TGA to a sponsor from entering their therapeutic good in the ARTG before conducting a clinical trial.

|  |  |
| --- | --- |
| Project Title/HREC Reference: | |
| Coordinating Principal Investigator: |  |

Before taking on the role of CPI, it is important to understand:

* What you need to have in place before you start a trial
* What aspects of the trial you need to review as the trial progresses

**Examples:**

SITE SPECIFIC RESPONSIBILITY ONLY. Where SESLHD is conducting the trial by recruiting and treating participants, but is not taking overall responsibility for trial oversight.

1. A pharmaceutical company is conducting a multi-site clinical trial worldwide. A facility in SESLHD is one of these site. The company has provided the protocol, funding and the investigational product. An NMA HREC (including but not limited to the SESLHD HREC) has authorised the study to commence in Australia. The SESLHD facility recruits and treats the participants and collects the data on behalf of the company. The company requires its staff to have clinical record access to monitor the study.
2. SESLHD employees have collaborated with employees of a University to design a clinical trial of a device. The University is the administrating institution for the NHMRC grant, and has entered into a collaborative clinical trial agreement with SESLHD. The University takes overall responsibility for the clinical trial, however the collaborative agreement specifies that some sponsor responsibilities (testing, specimen handling, record keeping, storage, monitoring) have been delegated to, or shared with SESLHD.

SPONSOR and SITE RESPONSIBILITY. Where SESLHD is conducting the trial by recruiting and treating participants, and is taking overall responsibility for trial oversight.

1. A NSWH grant is awarded to an SESLHD clinician holding a conjoint appointment at a Hospital and a University. The grant is administered by the University, but SESLHD is being asked to take on the role of sponsor to be conducted at the clinicians Hospital.
2. Emerging from a Quality & Safety audit an SESLHD employee designs a new medical procedure that requires testing in patients. Clinicians around Australia are interested in testing the change. SESLHD is being asked to conduct the trial as the sponsor.
3. An SESLHD employee designs a clinical trial to test a medicine in a population of the community, and the participants are seen at a shared precinct Clinical Research Facility. Funding for the trial has been received from a Foundation and the drug manufacturer is supplying the medicine.
4. A clinical trial has been designed by a senior clinician to test the usefulness of a procedure in the community. Participants are recruited through local facilities and the intervention takes place in the community (nursing home, aged care, community health centre). Seed funding for the project has been provided through SESLHD funds (innovation grants, SP&T). Even though the ‘site’ of the clinical trial is in the community, SESLHD takes responsibility for this trial.
5. A pharmaceutical or medical devices company provides SESLHD with a product to be used in a clinical trial but has no other involvement in the conduct of the trial. The LHD takes responsibly for the oversight and conduct of the trial.

This document sets out the allocation of clinical trial functions between the CPI and the Sponsor (SESLHD) for investigator-led or collaborative group clinical trials of therapeutic goods.

SESLHD will have overarching responsibility for the design and management of the research it sponsors but will delegate the following responsibilities to the CPI or a third party where appropriate (e.g. trial coordinating centre).

|  |  |  |  |
| --- | --- | --- | --- |
| **Responsibility** | **Res. Office** | **CPI** | **Third Party**  **(specify)** |
| Implement and maintain policies and procedures for the conduct and management of clinical trials | X |  |  |
| Ensure an independent expert review has demonstrated that the trial proposal is worthwhile, is of high scientific quality and represents good value for money | X |  |  |
| Ensure the CPI has adequate procedures in place for all trial management activities, (e.g. safety monitoring, randomisation, allocation concealment, blinding, data management and analysis) | X |  |  |
| Conduct an operational risk and feasibility assessments as part of the Sponsorship Agreement process | X |  |  |
| Ensure that the CPI and team have the necessary expertise and experience to conduct the trial | X |  |  |
| Ensure that the CPI has the resources needed to complete the trial successfully | X |  |  |
| Confirm provision of insurance and indemnity to cover liabilities, including those which may arise in relation to the design, management and conduct of the trial | X |  |  |
| Ensure all the roles and responsibilities for the clinical trial are delegated, agreed and documented appropriately, including clear agreements when SESLHD is co-Sponsoring the trial. | X |  |  |
| Oversee/sign-off all contracts/agreements with other external providers or third parties (e.g. pharmaceutical companies for supply of investigational product, external lab facilities, participating trial sites)  Where relevant, ensure clarity of arrangements for ownership of intellectual property | X |  |  |
| Ensure that appropriate, effective procedures and arrangements are kept in place for monitoring and audit of clinical trials to ensure adherence to GCP, the protocol and all regulatory requirements. Oversee the implementation of corrective and preventative measures when deficiencies are identified | X |  |  |
| Ensure that arrangements for making information about the trial publicly available are in place (i.e. registration through to final dissemination of trial results) |  |  |  |
| Be familiar with and comply with all relevant SESLHD policies/procedures relating to clinical trial management/conduct |  |  |  |
| Set-up and maintain the Trial Master File |  |  |  |
| Ensure that trials are registered on the ANZCTR (or other registry) and that appropriate plans for the dissemination of trial findings are in place. |  |  |  |
| Undertake/oversee the general management of the trial (including design, conduct and reporting) |  |  |  |
| Ensure that all requirements for therapeutic goods supplies are met (e.g. manufacture/packaging/labelling), involving pharmacy or medical engineering as appropriate. |  |  |  |
| Develop an appropriate strategy for independent trial oversight (e.g. Trial Management Group, Trial Steering Committee, Data Safety Monitoring Board) |  |  |  |
| If a Data Safety Monitoring Board is not warranted, ensure alternative mechanisms for ongoing safety monitoring are in place |  |  |  |
| Confirm sufficient resources are available (including a thorough feasibility to ensure the trial will recruit the required number of participants within the proposed timeframe).  For multi-centre trials, select investigators that are qualified by education, training and experience and with adequate resources to conduct the trial. |  |  |  |
| Confirm trial specific delegation of duty by maintaining a Sponsor Delegation Log and ensure staff members has the relevant training (e.g. GCP, protocol) before they undertake their role. Confirm each member of the trial team is aware of his/her trial-related duties. |  |  |  |
| Develop all relevant trial documentation (e.g. Protocol, Participant Information and Consent Form, Case Report Form, trial manuals/plans etc.) |  |  |  |
| Develop/obtain the Investigator's Brochure or where appropriate, the Product Information to be used for the trial and ensure that the reference safety information for identifying expectedness of adverse events is clearly identified. |  |  |  |
| Ensure all trial approvals and notification are in place before the trial commences (e.g. HREC, SSA, TGA ). |  |  |  |
| Oversee/arrange the set-up of a clinical trial database and ensure data management and analysis arrangements are in place (with appropriate statistician input). Ensure the collection of high quality data. |  |  |  |
| Ensure arrangements are in place for the effective financial management of the trial. |  |  |  |
| Prepare and submit amendments to the trial. |  |  |  |
| Report SUSARs, significant safety issues and urgent safety measures to the Research Office and all relevant bodies and manage all other Sponsor responsibilities for safety monitoring and reporting in accordance with NHMRC guidance. |  |  |  |
| Submit annual reports to the HREC and Research Office in accordance with Australian Guidance. |  |  |  |
| Report suspected serious breaches of GCP/protocol to the HREC and Research Office. |  |  |  |
| Provide the HREC and Research Office with a final summary report of the trial within 12 months of trial completion (completion being the date trial analysis begins). |  |  |  |
| Produce all necessary reports to funders and others. |  |  |  |
| Disseminate trial findings through publication/dissemination of trial results where applicable, following the evidence-based, minimum set of recommendations for reporting randomised trials ([Consort Website](http://www.consort-statement.org/)) |  |  |  |
| Disseminate research findings to participants. |  |  |  |
| Archive the Trial Master File and all source documentation and materials in accordance with the Australian Code. |  |  |  |

Name of Coordinating Principal Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_