ST VINCENT'S HOSPITAL
MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

RESEARCH GOVERNANCE UNIT
St. Vincent's Hospital (Melbourne)
Caritas Christi Hospice
St. George's Health Service
Prague House
Cambridge House
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INSURANCE, INDEMNITY, RESEARCH AGREEMENTS AND THE VMIA

Statement of Intent and Outcomes
The St Vincent's Hospital Human Research Ethics Committee is committed to fulfilling the Australian Code for the Responsible Conduct of Research (2018), The National Statement on Ethical Conduct in Human Research (2007 – Updated 2018) and the requirements of the Victorian Managed Insurance (VMIA) by providing a framework for the review of insurance, indemnity and research agreements.

Definitions
Nil

Procedure

As the Hospital's insurer, VMIA has released specific guidelines to guide the process of review for sponsored and collaborative clinical research, which involve clinical trials notification.

Clinical Trials Notification Form
Clinical trials which involve the use of unapproved drugs and devices, including those being used outside of their approved indications, must be notified to the Therapeutic Goods Administration in accordance with all statutory and regulatory requirements. This must be submitted to the reviewing HREC and the responsible institution.

Indemnity
All clinical trials involving a commercial Sponsor must provide indemnity in a form no less favourable than the current version Medicines Australia Form of Indemnity for Clinical Trials.

Both commercial Sponsorship and the indemnity must be provided by an Australian corporate entity. The reason for this is both legal and practical. If an indemnity is provided from an overseas-based corporation, with no assets or other presence in Australia, there are major (sometimes insurmountable) problems to be faced, particularly in relation to a corporation based in the USA, if the VMIA or a hospital has to enforce the indemnity. In many cases, enforcement proceedings would have to be instituted, at vast cost, in a foreign jurisdiction.

Where there is no Australian related corporate entity of the relevant overseas corporation, the services of an Australian corporate research organisation may be utilised to conduct the Trial in Australia. In that case, the research organisation is the Commercial Sponsor and must provide an indemnity. Any indemnity provided by a corporate research organisation

must be provided by it in its own right. It is not acceptable for the corporate research organisation to provide the indemnity as agent of the overseas company.

Where the involvement of a hospital is limited to ethical review by its HREC Clinical trials are sometimes conducted by private hospitals or practitioners in private practice. Some of these clinical trials are reviewed (for the purposes of obtaining any requisite ethical approval) by a public Hospital's HREC. The Commercial Sponsor's indemnity must name and fully indemnify the public hospital and its agents and servants for their participation and possible legal exposure in providing ethical review of a trial. An indemnity must be provided by the Commercial Sponsor in a form no less favourable than the "Form of Indemnity for Clinical Trials HREC Review Only"

Insurance
For all Sponsored clinical trials a current Public/Products Liability (or its equivalent) Certificate of Insurance from the Commercial Sponsor must be obtained.

To comply with the minimum insurance requirements, sponsored research must provide a copy of the certificate of currency (or insurance certificate) which contains the following information:

- The type of insurance – Public and Product Liability – or equivalent such as General Liability or Clinical Trials Insurance
- The full legal name of the Australian entity acting as the sponsor
- The full legal name of the insurer (which must be approved by the Australian Prudential Regulation Authority or a foreign equivalent). All insurers are required to hold Standard & Poor's financial rating of not less than 'A-'.
- The period of insurance
- That the insurance coverage allows for a minimum of A$10 million for any one occurrence and in the annual aggregate
- That the insurance coverage contains an excess/deductible, or self insured retention amount LESS than A$25,000 for each and every claim or series of claims arising out of one original cause.

Additional information regarding the level of insurance and indemnity required can be obtained from the Victorian Managed Insurance Authority (VMIA) Clinical Trials Guidelines and National Health and Medical Research Council Insurance Guidelines:

- https://www.vmia.vic.gov.au/~/media/internet/content-documents/risk/guides-and-publications/clinical-trials/clinical-trials-guide.pdf
- https://www.nhmrc.gov.au/about-us/resources/indemnity-and-insurance-arrangements-clinical-trials

Clinical Trial Research Agreements
The Sponsor of the trial is the company, institution or organisation that takes overall responsibility for the conduct of the Trial and usually initiates, organises and supports a clinical study of an investigational product in human subjects. The Sponsor must be an Australian company or entity.

A written agreement between St Vincent's Hospital and the Sponsor must always accompany a clinical trial; including, where relevant, a Commercial Sponsor which sets out the responsibilities of each party.

Medicines Australia Clinical Trial Research Agreements must be used for clinical trials. The use of the CTRAs should, in most cases, obviate the need for Institution to obtain extensive legal advice in relation to a Clinical Trial Research Agreement.

Commercially Sponsored CTRA
The Commercially Sponsored CTRA is to be used when an Australian pharmaceutical company or an Australian subsidiary of an international pharmaceutical company acts as the Sponsor for the purposes of the clinical trial.

The parties to the Commercially Sponsored CTRA are the Sponsor and the investigating institute.

The Principal Investigator is not a party to the CTRA. However, the Principal Investigator may sign the CTRA to acknowledge the obligations it imposes. The substantive provisions of the Commercially Sponsored CTRA must not be amended. Any minor amendments that may be required to accommodate any operational requirements of either party can be made through Schedule 7.

Corporate Research Organisation (CRO) CTRA
The CRO CTRA is to be used where an entity/ company that is not an Australian resident wishes to initiate a clinical trial and engages a CRO (that is an Australian entity) to act as the Sponsor for the purposes of the CTN application. The CRO becomes, and assumes all responsibilities and obligations that attach to, a Sponsor.

As Sponsor, the CRO must: Provide a Medicines Australia Form of Indemnity in favour of the Institution. Provide evidence of insurance arrangements that meet the minimum requirements of VMIA. It is acceptable for the CRO to be a named additional insured under an insurance policy of an organisation that is not an Australian entity/company.

The substantive provisions of the CRO CTRA must not be amended. Any minor amendments that may be required to accommodate any operational requirements of either party can be made through Schedule 7.

Collaborative Research Group (CRG) CTRA
The CRG CTRA is to be used when a collaborative/ cooperative research group is the Sponsor of the clinical trial. The substantive provisions of the CRG CTRA must not be amended. Any minor amendments that may be required to accommodate any operational requirements of either party can be made through Schedule 4.

Schedule 7 (Commercially Sponsored and CRO CTRA) and Schedule 4 (CRG CTRA)
Schedule 7 of the Commercially Sponsored CTRA and Schedule 4 of the CRG CTRA may be used to incorporate into a CTRA any unique operational requirements that are required by a party to allow the conduct of the clinical trial.

Schedules 7 and 4 are not to be used to substantially amend the CTRA or to introduce provisions that contradict or otherwise undermine the substantive provisions or intent of the CTRA.

The South Eastern Border States (SEBS) Committee has approved a number of Schedule 7 provisions submitted by individual commercial sponsors for the Commercially Sponsored CTRA. The approved Schedule 7 clauses have been issued to both the health services and the respective commercial sponsor. There will be commercial sponsors that have not submitted Schedule 7 provisions for review by the SEBS Committee. Given the substantial collection of Schedule **7** approved clauses, it is reasonable for an Institution to assess the acceptability of any request by such commercial sponsor against the existing approved Schedule 7 database provided by SEBS.

Subcontracting Commercially Sponsored and CRO CTRA
If a Commercial Sponsor or a CRO intends to subcontract any of its functions under a CTRA, the following clause can be used by way of Schedule 7:

"The Local Sponsor/CRO may subcontract any of its obligations under this Agreement, save for the obligations set out in clauses 5.1(8), 5.1(9) and 5.1(10) of the Agreement. The Local Sponsor remains responsible for all subcontracted obligations and is liable for all acts and omissions of any subcontractor as if they were the Local Sponsor's acts and omissions. No subcontractor will have any rights under this Agreement against the Institution or be entitled to receive any payment from the Institution."

CRG CTRA
If a CRG intends to subcontract any of its functions under a CTRA, the following clause can be used by way of Schedule 4:

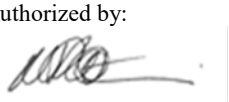
"The CRG may subcontract any of its obligations under this Agreement, save for the obligations set out in clause 10 of the Agreement. The CRG remains responsible for all subcontracted obligations and is liable for all acts and omissions of any subcontractor as if they were the CRG's acts and omissions. No subcontractor will have any rights under this Agreement against the Institution or be entitled to receive any payment from the Institution."

Associated Procedures/Instructions
Nil

Reference Documents

- The National Statement on Ethical Conduct in Research Involving Humans in accordance with the NHMRC Act, 2007 – Updated 2018 (Cth)
- Australian Code for the Responsible Conduct of Research (2018)
- VMIA Research Governance Toolkit
- VMIA Guidelines for Clinical Trials

Authorized by:



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