



VICTORIAN MANAGED INSURANCE
AUTHORITY

Taking care of risks

Guidelines for Clinical Trials

FOR VICTORIAN PUBLIC HOSPITALS

A close-up, low-angle photograph of a microscope's eyepiece and objective lenses, set against a vibrant blue background. The glass lenses are highly reflective, showing highlights and shadows that emphasize their spherical and cylindrical shapes. The overall composition is clean and professional, suggesting a focus on science and medicine.

2009

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The VMIA's privacy policy

The VMIA provides risk management services, insurance and insurance services to Victorian State Government departments and participating bodies as defined under the Victorian Managed Insurance Authority Act 1996.

The VMIA values the privacy of every individual's personal information and health information and is committed to protecting the information it holds and uses.

This privacy policy outlines how the VMIA manages personal and health information in accordance with the Information Privacy Act 2000 and the Health Records Act 2001. It applies to any personal information or health information provided to the VMIA and that VMIA collects, uses, discloses or handles about individuals from other sources.

This policy can be accessed by the public at our website: www.vmia.vic.gov.au.

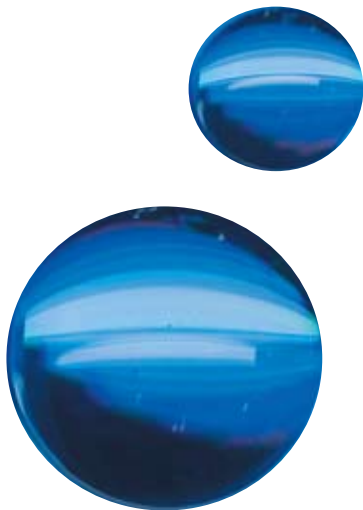


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● Introduction

This document has been prepared in order to assist ethics committees and investigators in the preparation and review of clinical trials. Adherence to the requirements outlined and use of the recommended forms and documentation contained in this document will help to ensure coverage under the Department of Human Services Insurance Program.

The template Participant Information and Consent Form (Attachment C) is recommended for your use by the Department of Human Services Victoria, as well as the Victorian Managed Insurance Authority (VMIA), for the purpose of continued insurance cover under the Medical Indemnity Policy. In all circumstances the Terms and Conditions of the relevant policy document shall prevail.

● VMIA CTN guidelines charter

These guidelines are intended to protect the interests of the States' public hospitals by establishing requirements for the conduct of investigator initiated and Commercially Sponsored studies. The Guidelines recognise that the relevant hospital assumes the risk attaching to the conduct of an investigator initiated study. The Guidelines also recognise that, in relation to Commercially Sponsored studies, that risk must be shared with the Commercial Sponsor that stands to gain a financial benefit from the study. For Commercially Sponsored studies, it is important that the Clinical Trial Research Agreement with commercial entities adequately addresses the issue of insurance and that the provision of indemnities is fair and equitable. The VMIA has formulated these guidelines to assist its client base in achieving this objective. Compliance in this regard will ensure that cover under the VMIA's Medical Indemnity Policy is not jeopardised.

The VMIA is keen to promote and be an integral part of the clinical trial scene within the State of Victoria; and fully supports the State Government's agenda whilst ensuring that all clinical trial activities deliver the desirable clinical outcomes without placing the State's and patients' interests under any undue risk.

These Guidelines, the standard Clinical Trial Research Agreements, the First Time In Human (FTIH) protocol and other relevant information are available on the VMIA website under Public Healthcare > Clinical Trials.

To access to the FTIH expert reviewer database, visit www.health.vic.gov.au/ethics.

● VMIA contacts

Postal address: Level 30, 35 Collins Street
Melbourne, Victoria, 3000
Main Telephone: 03 9270 6900
Main Fax: 03 9270 9270
Website: www.vmia.vic.gov.au

General enquiries

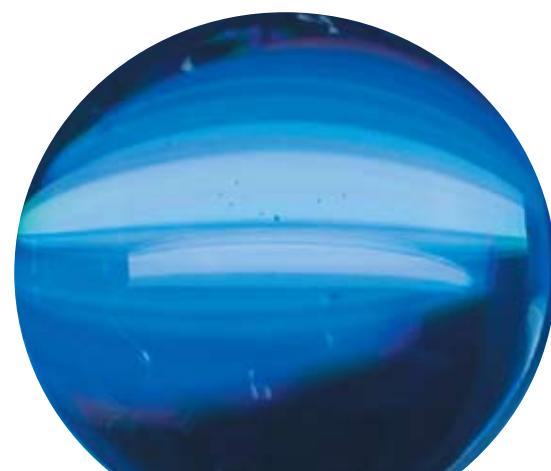
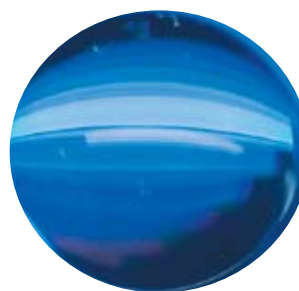
Mr Bill Karanatsios
Client Relationship Manager
Public Healthcare Insurance Program
Telephone: 03 9270 6926
Email: b.karanatsios@vmia.vic.gov.au

Claims and claims litigation

Ms Mary MacLeod
Claims Manager
Telephone: 03 9270 6961
Email: m.macleod@vmia.vic.gov.au

Ms Maria Palamara
Claims Executive
Telephone: 03 9270 6820
Email: m.palamara@vmia.vic.gov.au

Ms Shani Salier
Claims Executive
Telephone: 03 9270 6928
Email: s.salier@vmia.vic.gov.au



● Glossary

1. Investigator Initiated Trials

An investigator initiated trial is a clinical trial that has the following characteristics:

- A pharmaceutical/device company is not acting as the Sponsor for the purposes of the CTN Scheme application.
- A pharmaceutical/device company is not directly funding the conduct of the study, that is, making payment to the relevant hospital or investigator.
- The clinical trial addresses relevant clinical questions and not industry needs.
- The Principal Investigator or the Hospital/ Institution is the primary author and custodian of the clinical trial protocol.

There will be investigator initiated trials which will have some industry funding or industry contributions. Such funding arrangements must be declared in the protocol submission to ensure that the clinical trial retains its “investigator initiated” status under the VMIA policy.

Clinical trials that are initiated by co-operative/ collaborative research groups are treated as investigator initiated, provided they meet the requirements for co-operative studies set out in these Guidelines.

2. Commercially Sponsored Trials:

A Commercially Sponsored trial is a clinical trial that has the following characteristics:

- It is initiated by a pharmaceutical/device company or other commercial entity and not by an investigator at an insured Victorian public health service.
- The Trial is conducted to investigate a drug/ device for commercial exploitation by its manufacturer/sponsor.
- The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.

● Clinical Trials Insurance Requirements

To ensure Hospitals/Institutions participating in the Clinical Trials Notification (CTN) Scheme do not jeopardise their entitlement to indemnity under the policies arranged by the VMIA, it is essential that they adhere to the following requirements.

These Guidelines specify minimum requirements and relate to 5 different aspects of clinical trials:

1. Liability assumed by agreement for which your institution may or may not be insured.
2. The agreement between Hospital/Institution and Sponsor.
3. Human Research Ethics Committees (HREC).
4. Indemnity and insurance requirements.
5. Adverse Events.

Liability assumed by agreement

It is important to ensure that the Hospital, HREC and investigator do not do, or omit to do, anything which might disentitle any, or all of them, to such indemnity as could otherwise be available under the Medical Indemnity and Public Liability Policies.

Hospitals/Institutions should exercise caution when entering into Clinical Trial Research Agreements with pharmaceutical companies or research organisations acting as the Sponsor for the conduct of the Trial. In particular, the Hospital/Institution may jeopardise its coverage under the Department of Human Services’ (DHS) Malpractice Policy if it assumes liabilities which would otherwise attach to the pharmaceutical company or research organisation(s). Two pro forma Medicines Australia Forms of Indemnity for clinical trials (*refer Attachments A and B*) have been developed in conjunction with DHS. The VMIA recommends the use of these indemnity forms to ensure that continued insurance cover under the VMIA’s Medical Indemnity Policy applies (see “*Insurance and indemnity requirements*”).

Clinical Trial Research Agreements

There must be a written agreement between the Hospital/Institution and the Sponsor - including, where relevant, a Commercial Sponsor which sets out the responsibilities of each party.

The VMIA in collaboration with interstate health departments and industry agencies, has developed a set of standard Clinical Trial Research Agreements (CTRA) to be used by Hospitals/Institutions. The CTAs contain common, standard provisions, but are sufficiently flexible to accommodate for individual Local Sponsor and

international organisation operational requirements. The use of the CTRAs should, in most cases, obviate the need for Hospitals/Institutions to obtain extensive legal advice in relation to a Clinical Trial Research Agreement.

The information below has been provided to assist Hospitals/Institutions in selecting and using the appropriate CTRA for a particular study.

Sponsor of the Trial

The Local 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 Local Sponsor of the Trial must be an Australian company or entity.**

The Local Sponsor is the Australian entity that endorses the CTN Application. The Local Sponsor must provide an indemnity (*in the Medicines Australia format*) and provide evidence it is covered by the requisite insurance arrangements for the conduct of the clinical trial.

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 Local Sponsor for the purposes of the clinical trial.
- The parties to the Commercially Sponsored CTRA are the Local 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 Local Sponsor for the purposes of the CTN application. The CRO becomes, and assumes all responsibilities and obligations that attach to, a Local Sponsor.

As Local Sponsor, the CRO must:

- Provide a Medicines Australia Form of Indemnity in favour of the Hospital/Institution.

- Provide evidence of insurance arrangements that meet the minimum requirements set out in these Guidelines. 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 VMIA 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 VMIA. Given the substantial collection of **Schedule 7** approved clauses, it is reasonable for a Hospital/Institution to assess the acceptability of any request by such commercial sponsor against the existing approved **Schedule 7** database provided to your institute. This should provide a Hospital/Institution with the ability to suggest identified alternate VMIA approved clauses. If you suggest such alternate clauses to a Sponsor other than the Sponsor to which the original approval applies, you must ensure that the clauses are used in a manner that does not identify the original Sponsor and does not disclose confidential information of any Sponsor.

Unless it has the commercial sponsor's permission, a Hospital/Institution must not provide details of that commercial sponsor's Schedule 7 to another commercial sponsor or any other organisation.

At all times, Schedule 7 submissions of each Commercial Sponsor should be treated as commercial in confidence information.

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.

The CTAs encompass all the relevant minimum requirements set out in the VMIA CTN Guidelines. The VMIA strongly encourages its insureds to use the CTAs for all sponsored trials to ensure that cover under the VMIA policy is not compromised.

Requirements for drug and device trials conducted under the CTN Scheme

General Requirements

For all clinical trials which are conducted under the CTN Scheme, the Hospital/Institution must ensure that the Therapeutic Goods Administration has been notified in accordance with all statutory and regulatory requirements, in respect of the Trial drug or device.

The following clinical trials conducted under the CTN scheme must be submitted to the VMIA's lawyers, DLA Phillips Fox, for insurance coverage approval:

1. All clinical drug or device trials which have no Commercial Sponsorship (that is, Hospital/Institution or investigator initiated trials and includes co-operative collaborative group studies - see page 9).
2. All Commercially Sponsored Phase I and Phase II clinical drug trials and all Commercially Sponsored device trials.
3. Any Commercially Sponsored Phase III and IV clinical drug trials which do not comply with the minimum requirements outlined in these guidelines. These minimum requirements include:
 - The drug must have been approved by a competent regulatory authority for marketing or clinical trial purposes
 - The Trial is classified as a Phase III or subsequent trial
 - The Commercial Sponsor has provided an indemnity in acceptable form, complying generally with the standard Medicines Australia format (*refer to Attachments A and B*).

Hospitals/Institutions are not required to submit for approval any clinical trials not conducted under the CTN Scheme (eg non drug/device trials, evidence – based studies or those conducted under the CTX Scheme).

These studies are automatically covered under the VMIA's insurance arrangements, provided that Hospitals/Institutions comply with the terms of all relevant policies and any legal and regulatory requirements concerning the conduct of those studies. However, such trials should- *as far as is relevant*- adopt the *pro forma* Participant Information and Consent Forms as set out in Attachment C and adhere to the general requirements for HRECs as set out under the Human Research Ethics Committee (HREC) section below.

● VMIA Clinical Trial Notification Requirements

Phase I and II clinical drug trials and all device trials

- i. Phase I and Phase II clinical drug trials and all device trials to be conducted by a Hospital/Institution under the CTN Scheme must be carried out in accordance with the internal guidelines and requirements of the Hospital/Institution. Ethical approval for a proposed trial must be obtained from the Hospital's/Institution's HREC in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2007) ("the NHMRC National Statement")
- ii. Prior to the commencement of a Phase I or a Phase II clinical drug trial or any device trial, a copy of the following documents must be provided to Dr Arthur Rallis at DLA Phillips Fox Lawyers, Level 17, 140 William Street, Melbourne 3000: the registration *pro forma*, lay summary, scientific summary, patient information sheet and patient consent form and, for Commercially Sponsored trials, an indemnity provided by the Commercial Sponsor and a certificate of insurance evidencing the Commercial Sponsor's insurance arrangements in respect of the Trial. A copy of your covering letter to DLA Phillips Fox (*not the documentation*) should be forwarded to the VMIA.

In order to expedite the commencement of a clinical trial, you may submit the above documentation to DLA Phillips Fox prior to review of the trial by the Hospital's/Institution's HREC. Any approval given by DLA Phillips Fox is conditional upon HREC approving the clinical trial. If, following HREC review, significant changes are made to any of the documents relating to a clinical trial that has been approved by DLA Phillips Fox, you must resubmit the relevant document/s for approval by DLA Phillips.

All documentation required to be submitted to Dr Arthur Rallis at DLA Phillips Fox can be submitted in electronic format to: arthur.rallis@dlaphillipsfox.com.

It is not necessary to submit the protocol unless requested to do so.

- iii. DLA Phillips Fox will provide its advice within 14 days after it receives the submitted trial. A trial will be deemed to have been approved by the VMIA unless, within 14 days after DLA Phillips Fox receive the documents referred to above, they notify your hospital in writing to the contrary.

iv. Important Note: Failure to carry out recommendations made by DLA Phillips Fox may invalidate your policy coverage.

Requirements for non-Commercially Sponsored or institution/investigator initiated trials

Any clinical trial involving a drug or device not approved for marketing in Australia (or approved for an indication other than that proposed in the clinical trial) and for which there is no Commercial Sponsorship, requires approval from the VMIA and must be submitted to the VMIA and comply with the additional requirements set out above in relation to Phase I and II clinical drug trials and all device trials.

Phase III or IV clinical drug trials

The following minimum requirements must be observed in relation to commercially sponsored Phase III or IV clinical drug trials:

- i. A Hospital/Institution is not required to submit for approval any Commercially Sponsored Phase III and IV drug trial, provided the trial complies with the requirements for Phase III and IV drug trials guidelines set out in paragraphs ii to vii below. If it complies, the Trial will be automatically covered by the Public Liability and Medical Indemnity Policies. If it does not comply, a copy of the following documents must be provided to Arthur Rallis at DLA Phillips Fox Lawyers, Level 17, 140 William Street, Melbourne Victoria, Australia 3000 in relation to that Trial:
 - the registration *pro forma*
 - lay summary
 - scientific summary
 - patient information sheet and patient consent form
 - for Commercially Sponsored trials, an indemnity provided by the Commercial Sponsor and a certificate of insurance evidencing the Commercial Sponsor's insurance arrangements in respect of the Trial.
 - A copy of your covering letter to DLA Phillips Fox (*not the documentation*) should be forwarded to the VMIA.

All documentation required to be submitted to Dr Arthur Rallis at DLA Phillips Fox can be submitted in electronic format to the following email address: arthur.rallis@dlaphillipsfox.com.

It is not necessary to submit the protocol unless requested to do so.

- ii. Phase III and Phase IV clinical drug trials to be conducted by a Hospital/Institution under the CTN Scheme must be carried out in accordance with the internal guidelines and requirements of the Hospital/Institution. Ethical approval for a proposed trial must be obtained from the Hospital's/Institution's HREC in accordance with the NHMRC National Statement.
 - iii. The drug must have been approved for marketing or clinical trial by a Competent Regulatory Authority for the use, dose, duration of treatment and broad patient group proposed for the clinical trial. 'Competent Regulatory Authority' means the Therapeutic Goods Administration (Australia), Food and Drug Administration (USA), Medicines Control Authority (UK), Swedish Medicines Agency or such other Authority as may be approved in writing by DLA Phillips Fox on behalf of the VMIA.
 - iv. The clinical trial must be in Phase III or IV of the generally accepted clinical trial classification, that is:
 - a. data from Phase II studies indicate that the potential benefits of the Trial outweigh possible hazards; and
 - b. the purpose of the Trial is to ascertain whether the drug or device confers clinical benefits in the disease states for which effectiveness is to be claimed, with an acceptable incidence and nature of adverse effects.
 - v. The Commercial Sponsor, if any, must provide an indemnity in terms that are no less favourable than those set out in the insurance and indemnity requirements section below.
 - vi. The Commercial Sponsor, if any, must comply generally with the insurance and indemnity requirements below.
 - vii. The Protocol for the administration of the Trial must conform with the NHMRC's National Statement, as amended from time to time.
- ii. The HREC, in providing ethical approval for the conduct of clinical trials, must comply with the minimum requirements as set out in the NHMRC's National Statement.
 - iii. The HREC must ensure that a clinical trial of a medical procedure that involves the recruitment of participants aged 18 years or over who are incapable of giving consent must comply with the *Guardianship and Administration Act 1986* (Vic) (GAA).

In particular, the consent procedure of such clinical trial must comply with the four step procedure prescribed in Part 4A of the GAA. In this regard where the investigators will seek the consent of the participant's person responsible, the VMIA recommends the use of the Consent Form – Person Responsible that forms Template D of these Guidelines.
 - iv. The NHMRC National Statement contemplates the possibility that a HREC may approve a clinical trial to be conducted outside the approving Institution by an investigator who is not connected to the Institution. In such cases, where the role of the HREC is to provide ethical approval only and where the conduct of such trials do not involve public patients, additional requirements may apply with respect to any Indemnity provided. (*See Indemnity and Insurance Special Requirement 1*).
 - v. HRECs have the responsibility of ensuring that the conduct of all research approved by the HREC is monitored in accordance with the provisions set out in the NHMRC National Statement and the Trial Protocol. This role is all the more important when the research is conducted outside the walls of the institution, because the usual lines of supervision and responsibility do not apply. Therefore, HRECs must take greater than usual care in setting up supervision arrangements for extra-mural trials. (*Refer to Indemnity and Insurance Special Requirement 2*).

The Human Research Ethics Committee (HREC)

The following minimum requirements are to be observed in relation to HRECs:

- i. The HREC must be constituted under hospital regulations and in accordance with the NHMRC's National Statement, as amended from time to time. The HREC must comprise and contain the minimum number of members as set out in the National Statement.

Indemnity and Insurance Requirements

In respect of these Commercially Sponsored clinical trials, the VMIA has a number of specific requirements regarding indemnity and insurance as outlined below.

General requirements

An indemnity must be provided by the Commercial Sponsor in a form no less favourable than the current version Medicines Australia Form of Indemnity for Clinical Trials (refer Attachments A and B).

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 have 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.

Any words which purport to suggest any type of agency arrangement are not acceptable.

Special Requirements

1. 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" (*refer to Attachment B*).

HREC's providing ethical approval only must implement appropriate monitoring and surveillance mechanisms to fulfil their obligations under the NHMRC National Statement.

2. Where a third party seeks to be indemnified by the Commercial Sponsor

For various reasons, parties other than the public hospital at which the clinical trial is to be conducted may seek to be indemnified by the Commercial Sponsor.

Where a third party such as a research or other body or organisation involved in a clinical trial wishes to be indemnified by the Commercial Sponsor, a separate Form of Indemnity should be used for each party that is indemnified. Such third party should **not** be included in the definition of "the Indemnified Party" in the Form of Indemnity naming the public hospital.

A Hospital's Research Foundation and/or its HREC are sometimes included in the definition of "the Indemnified Party" in the indemnity provided by a Commercial Sponsor to a public Hospital. It is unnecessary to include a Hospital's Research Foundation in the definition of "the Indemnified Party" as this party generally falls within the definition of "agents" in clause 9 of the standard Medicines Australia indemnity and is therefore covered under the indemnity save for the particular case outlined under item 1 above. It is also unnecessary to include a Hospital's HREC in this definition as clause 3 of the standard Medicines Australia indemnity states that the Sponsor indemnifies members of, and advisors to, the relevant HREC.

Certificate of Insurance

In order to streamline the approval process for sponsor's insurance arrangements, the VMIA has approved in advance a number of sponsors' insurance arrangements. The VMIA has previously provided details of each sponsor and its insurance arrangements that have been so approved to insureds. If a sponsor submits to a Hospital/Institution a certificate of currency that is identical to the certificate that has been approved by the VMIA, the Hospital/Institution can proceed on the basis of that approval and does not need to submit the certificate to the VMIA.

In all cases, a current Public/Products Liability (or its equivalent) Certificate of Insurance from the Commercial Sponsor should be obtained as a matter of general prudence. At a minimum, the Certificate of Insurance must:

- specifically name the Australian corporate entity acting as Commercial Sponsor as a named insured under the relevant insurance policy
- evidence the existence of an insurance policy which covers the conduct of the relevant clinical trial in Australia
- be through an insurer either approved by the Australian Prudential Regulation Authority or an overseas insurer with a minimum credit rating of Standard and Poors (or equivalent) of A - or better
- evidence that the policy will be current throughout the entire period in which the clinical trial is conducted
- contain insurance coverage for a minimum amount AUD\$10 million for any one occurrence and in the annual aggregate. The Insurance Policy must not contain an excess/deductible or self insured retention amount greater than AUD\$25,000 for each and every claim or series of claims arising out of one originating cause. The VMIA may exercise its discretion by approving insurance arrangements for less than \$10 million and/or a deductible greater than \$25,000. This consideration may include such matters as the following:
 - The level of clinical risk associated with the Trial
 - The financial strength of the insurer
 - The financial strength of the commercial clinical trial sponsor.

A Commercial Sponsor may satisfy the requirement to provide evidence of its insurance arrangements if it is a named insured on a policy effected by another entity whether local or overseas. Alternatively, if the certificate of insurance names the Commercial Sponsor's overseas parent as insured and states that the relevant policy covers all subsidiaries of that parent, then such parent company must provide written confirmation that the Australian corporate entity acting as Commercial Sponsor is a wholly owned, operated or controlled subsidiary company of the parent and that such subsidiary is also a named insured under the relevant insurance policy for the purpose of the conduct of the Trial in Australia.

Hospitals **must** seek approval from the VMIA if any of the above requirements cannot be met.

Serious adverse events

All Hospitals/Institutions must comply with the requirements of the National Statement regarding the disclosure of the following:

- serious or unexpected adverse effects on participants
- proposed changes in the research protocol
- unforeseen events that might affect continued ethical acceptability of the Trial.

A serious adverse event is defined in Appendix 3 to the NHMRC National Statement as including any untoward medical occurrence that:

- results in death
- is life threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity; or
- is a congenital anomaly / birth defect.

Reports of serious adverse events, [or which relate to a claim made against the Hospital/Institution (or a member of its staff) and/or the occurrence of circumstances which may subsequently give rise to a claim against a Hospital/Institution], must be reported to VMIA in accordance with the provisions of the VMIA Public Liability and Medical Indemnity Policies. Failure to give proper, prompt notification of any circumstance likely to give rise to a claim or the making of a claim may compromise insurance coverage for both the Hospital/Institution and/or a member of its staff.

VMIA recommends the use of the pro forma Adverse Events Report Form in Attachment D.

Serious adverse events which are "possibly" drug/device related, or which require a change to the Participant Information and Consent Form or the conduct of the Trial should be promptly notified to the VMIA.

Hospitals/Institutions are also reminded of their obligations under a Clinical Trial Research Agreement, where relevant, to promptly notify the Sponsor of the occurrence of any significant adverse event and/or the Commercial Sponsor pursuant to the terms of an Indemnity (see *Insurance and Indemnity Requirements above*).

All other events that do not fall within the above categories do not need to be reported to the VMIA.

● Co-operative/Collaborative Studies

Co-operative studies have been earmarked as playing a leading role in clinical cancer research in the years to come, with countries comparable to Australia greatly increasing their investment in this clinical research sector/stream.

As the emergence of co-operative studies will be more apparent overtime both abroad and in Australia, the need to define the insurable boundaries and requirements for such studies initiated or conducted in Australia is paramount.

Traditionally, the VMIA has treated co-operative studies as investigator initiated studies. In order for co-operative trials to continue to be classified as investigator initiated studies, the study must have the following characteristics:

1. The research must address relevant clinical questions and not pharmaceutical/device industry or commercial needs.
2. The co-operative group must declare the nature of any sponsorship from a pharmaceutical entity or any other entity that may directly benefit commercially from the research outcomes.
3. The co-operative group must be the primary author and custodian of the clinical trial protocol.

While the VMIA does not prescribe specific insurance requirements for co-operative or collaborative research groups, it expects that such group maintain adequate insurance as is reasonable and necessary to provide indemnity to it in relation to any liability which it may incur in conducting the Study or performing its obligations under the CRG CTRA.

If the co-operative study does not meet the above criteria, it is classified as a Commercially Sponsored trial and must meet the insurance and indemnity requirements for Commercially Sponsored studies.

● Mutual Acceptance

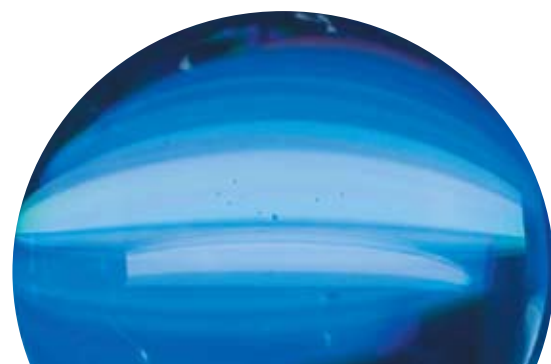
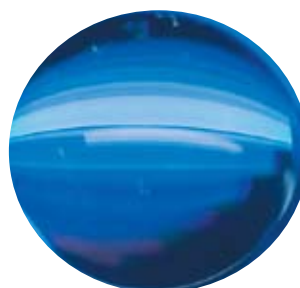
The Mutual Acceptance Program (MAP) was developed in order to expedite the ethical approval process for multi-centre studies. The VMIA supports the MAP.

Under the MAP, a nominated primary site for a multi-centre study may submit one set of clinical trial documentation to DLA Phillips Fox for review in accordance with the following process:

1. The primary site is nominated to perform the primary review for a particular study.
2. Each accepting site accepts or endorses the primary site's approval for a particular trial.
3. The primary site must notify DLA Phillips Fox of the MAP status of the study and the names and site study identification numbers of all accepting sites.
4. The primary site must submit the relevant documents for the study to DLA Phillips Fox for review. It is not necessary to submit all sets of documents for each accepting site, provided all of those documents are consistent with the originally approved primary site documents, save for site specific changes.

The participants under the MAP have an obligation to ensure that:

1. Any amendments that have been suggested by DLA Phillips Fox are consistently implemented across all accepting sites; and
2. DLA Phillips Fox is promptly notified of any inconsistencies in documentation between the various sites.



● Attachment A

A Pro Forma Medicines Australia Form of Indemnity for Clinical Trials

Standard

For use where the Indemnified Party is providing premises for the conduct of the Study and HREC Review, or is providing premises only.

NOTE: there is a separate Form of Indemnity for use where the Indemnified Party is providing HREC review ONLY of the study.

This Form has been developed by Medicines Australia and is an adaptation of the form used by The Association of the British Pharmaceutical Industry (ABPI), for use in Australia. It is to be regarded as the basis for agreements between pharmaceutical companies sponsoring clinical studies and the institution that hosts the study to be conducted. Non-members of Medicines Australia are encouraged to use this Form of Indemnity.

To: *[Name and address of the legal entity (hospital, institution or authority) in which the Study is to be conducted ("the Indemnified Party")].*

Only a single legal entity should be named. Where more than one legal entity is to be indemnified, separate Forms of Indemnity should be used for each legal entity to be indemnified.

From: *[Name, registered address and Australian Business Number of sponsoring company] ("the Sponsor").*

Re: *Clinical Study No. [], [protocol title including name of product]*

1. The Indemnified Party agrees to participate in the above sponsored study ("the Study") involving [{patients of the Indemnified Party} {non-patient volunteers}] ("the Subjects") to be conducted by [name of investigator(s)] ("the Investigator") in accordance with the protocol annexed, as amended in writing from time to time with the agreement of the Sponsor and the Indemnified Party ("the Protocol"). The Sponsor confirms that it is a term of its agreement with the Investigator that the Investigator shall obtain all necessary approvals from the applicable Human Research Ethics Committee ("HREC") and the Indemnified Party, where appropriate.
2. The Indemnified Party agrees to participate by allowing the Study to be undertaken on its premises or as otherwise agreed, utilising such facilities, personnel and equipment as may reasonably be required for the Study.
3. In consideration of such participation by the Indemnified Party, subject to paragraph 4 below, the Sponsor indemnifies and holds harmless the Indemnified Party and its employees, agents, and members of and advisors to its HREC in respect of and against all claims and proceedings (including any settlements or ex gratia payments made with the consent of the parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise) by or on behalf of Subjects (including their dependants and children injured in utero through the participation of the child's mother in the Study) against the Indemnified Party or any of its employees, agents or members of and advisors to its HREC for personal injury (including death) to Subjects (and children injured in utero through the participation of the child's mother in the Study) arising out of or relating to the administration and/or use of the product(s) under investigation or any clinical intervention or procedure provided for or required by the Protocol to which the Subjects would not have been exposed but for the participation of the Subjects in the Study.
4. The above indemnity by the Sponsor will not apply to any such claim or proceeding referred to in paragraph 3 above:
 - (1) to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Indemnified Party or any of its employees, agents or members of and advisors to its HREC.
 - (2) to the extent that such personal injury (including death) is caused by the failure of the Indemnified Party, its employees, or agents to conduct the Study strictly in accordance with the Protocol.

- (3) unless as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Indemnified Party notifies it to the Sponsor in writing and at the Sponsor's request, and cost, has permitted the Sponsor to have full care and control of the claim or proceeding using legal representation of its own choosing.
- (4) if the Indemnified Party, its employees, agents, or members of and advisors to its HREC have made any admission in respect of any such claim or proceeding or taken any action relating to any such claim or proceeding prejudicial to the defence of any such claim or proceeding without the written consent of the Sponsor.

Such consent will not be unreasonably withheld. This condition will not be treated as breached by any statement properly made by the Indemnified Party, its employees, agents, or members of and advisors to the HREC in connection with the operation of the Indemnified Party's internal complaint procedures, accident reporting and quality assurance procedures or disciplinary procedures or where such statement is required by law.

- 5. The Sponsor will keep the Indemnified Party and its legal advisers fully informed of the progress of any such claim or proceeding, consult fully with the Indemnified Party on the nature of any defence to be advanced and not settle any such claim or proceeding without the written approval of the Indemnified Party which approval is not to be unreasonably withheld.
- 6. Without prejudice to the provisions of paragraph 4(3) and 4(4) above, the Indemnified Party will use reasonable endeavors to inform the Sponsor promptly of any circumstances of which it has knowledge and which may reasonably be thought likely to give rise to any such claim or proceeding and will keep the Sponsor informed of developments in relation to any such circumstances even where the Indemnified Party decides not to claim indemnity from the Sponsor. Likewise, the Sponsor will use reasonable endeavors to inform the Indemnified Party of any such circumstances and will keep the Indemnified Party informed of developments in relation to any such claim or proceeding made or brought against the Sponsor alone.
- 7. The Sponsor and the Indemnified Party will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Subjects (including their dependants and children injured in utero through the participation of the child's mother in the Study).
- 8. Without prejudice to the foregoing, if injury is suffered by a Subject while participating in the Study, the Sponsor agrees to adhere to the "Guidelines for Compensation for Injury Resulting From Participation in a Company-sponsored Clinical Trial" published by Medicines Australia and will request the Investigator to make clear to the Subjects that the Study is being conducted subject to those Guidelines.
- 9. For the purpose of this indemnity, the expression "agents" is deemed to include, but is not limited to:
 - (1) any person carrying out activities for the Indemnified Party under a contract connected with such of the Indemnified Party's facilities and equipment as are made available for the Study under paragraph 2 above; and
 - (2) any health professional providing services to the Indemnified Party under a contract for services or otherwise.
- 10. This indemnity will be governed by and construed in accordance with the laws applicable in the State or Territory in which the Indemnified Party is established.

DATED the _____ day of _____ in the year _____ .

SIGNED by a duly authorised representative of the Sponsor

(Signature)

(Position)

SIGNED by the Chief Executive or a duly authorised representative of the Indemnified Party

(Signature)

(Position)

● Attachment B

Form of Indemnity for Clinical Trials

MEDICINES AUSTRALIA FORM OF INDEMNITY FOR CLINICAL TRIALS HREC REVIEW ONLY

(For use where the Indemnified Party is providing HREC review ONLY of the Study)

This Form has been developed by Medicines Australia and is an adaptation of the form used by The Association of the British Pharmaceutical Industry (ABPI), for use in Australia. It is to be regarded as the basis for agreements between pharmaceutical companies sponsoring clinical studies and the institution that has oversight of the study to be conducted. Non-members of Medicines Australia are encouraged to use this Form of Indemnity.

To: *[Name and address of the legal entity (hospital, institution or authority) which is providing HREC review only of the Study] ("the Indemnified Party")*

Only a single legal entity should be named. Where more than one legal entity is to be indemnified, separate Forms of Indemnity should be used for each legal entity to be indemnified.

From: *[Name, registered address and Australian Business Number of sponsoring company] ("the Sponsor")*

Re: Clinical Study No. [], *[protocol title including name of product]*

1. The Indemnified Party agrees to participate in the above sponsored study ("the Study") involving [{patients of [name of hospital, institution or site]} {non-patient volunteers}] ("the Subjects") to be conducted by [name of investigator(s)] ("the Investigator") in accordance with the protocol annexed, as amended in writing from time to time with the agreement of the Sponsor and the Indemnified Party ("the Protocol"). The Sponsor confirms that it is a term of its agreement with the Investigator that the Investigator shall obtain all necessary approvals from the applicable Human Research Ethics Committee ("HREC") and the Indemnified Party, where appropriate.
2. The Indemnified Party agrees to participate by making its HREC available to provide review, approval and oversight of the conduct of the Study in accordance with the requirements of the NHMRC National Statement on Ethical Conduct in Human Research (2007).
3. In consideration of such participation by the Indemnified Party, subject to paragraph 4 below, the Sponsor indemnifies and holds harmless the Indemnified Party and its employees, agents and members of and advisors to its HREC in respect of and against all claims and proceedings (including any settlements or ex gratia payments made with the consent of the parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise) by or on behalf of Subjects (including their dependants and children injured in utero through the participation of the child's mother in the Study) against the Indemnified Party or any of its employees, agents or members of and advisors to its HREC for personal injury (including death) to Subjects (and children injured in utero through the participation of the child's mother in the Study) arising out of or relating to the administration and/or use of the product(s) under investigation or any clinical intervention or procedure provided for or required by the Protocol to which the Subjects would not have been exposed but for the participation of the Subjects in the Study.
4. The above indemnity by the Sponsor will not apply to any such claim or proceeding referred to in paragraph 3 above:
 - (1) to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Indemnified Party or any of its employees, agents or members of or advisors to the HREC.
 - (2) unless as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Indemnified Party notifies it to the Sponsor in writing and at the Sponsor's request, and cost, has permitted the Sponsor to have full care and control of the claim or proceeding using legal representation of its own choosing.
 - (3) if the Indemnified Party, its employees, agents, or members of and advisors to its HREC have made any admission in respect of any such claim or proceeding or taken any action relating to any such claim or proceeding prejudicial to the defence of any such claim or proceeding without the written consent of the

Sponsor. Such consent will not be unreasonably withheld. This condition will not be treated as breached by any statement properly made by members of and advisors to the HREC in connection with the operation of the Indemnified Party's internal complaint procedures, accident reporting and quality assurance procedures or disciplinary procedures or where such statement is required by law.

5. The Sponsor will keep the Indemnified Party and its legal advisers fully informed of the progress of any such claim or proceeding, consult fully with the Indemnified Party on the nature of any defence to be advanced and not settle any such claim or proceeding without the written approval of the Indemnified Party which approval is not to be unreasonably withheld.
6. Without prejudice to the provisions of paragraph 4(2) and 4(3) above, the Indemnified Party will use reasonable endeavors to inform the Sponsor promptly of any circumstances of which it has knowledge and which may reasonably be thought likely to give rise to any such claim or proceeding and will keep the Sponsor informed of developments in relation to any such circumstances even where the Indemnified Party decides not to claim indemnity from the Sponsor. Likewise, the Sponsor will use reasonable endeavors to inform the Indemnified Party of any such circumstances and will keep the Indemnified Party informed of developments in relation to any such claim or proceeding made or brought against the Sponsor alone.
7. The Sponsor and the Indemnified Party will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Subjects (including their dependants and children injured in utero through the participation of the child's mother in the Study).
8. Without prejudice to the foregoing, if injury is suffered by a Subject while participating in the Study, the Sponsor agrees to adhere to the "Guidelines for Compensation for Injury Resulting From Participation in a Company-sponsored Clinical Trial" published by Medicines Australia and will request the Investigator to make clear to the Subjects that the Study is being conducted subject to those Guidelines.
9. For the purpose of this indemnity, the expression "agents" is deemed to include, but is not limited to any health professional providing services to the Indemnified Party under a contract for services or otherwise
10. This indemnity will be governed by and construed in accordance with the laws applicable in the State or Territory in which the Indemnified Party is established.

DATED the day of in the year .

SIGNED by a duly authorised representative of the Sponsor

(Signature)

(Position)

SIGNED by the Chief Executive or a duly authorised representative of the Indemnified Party

(Signature)

(Position)

● Attachment C

Participant Information and Consent Form

This Participant Information and Consent Form is endorsed by the Department of Human Services, Victoria, as well as VMIA for the purpose of insurance coverage under the Department of Human Services Malpractice Policy.

Filling out this Form

Recommended text is in plain type.

Instructions for preparation of the document are in *bold, italic 14-pt type in a different font*. You should delete these comments from the final document.

For projects that do not involve clinical drug or device trials or collection of tissue, use Template A.

Headed with Institution's name or on Institution's Letterhead

Copy from here >

Participant Information and Consent Form

Version # Dated #

Site ##

Full Project Title:

Principal Researcher:

Associate Researcher(s):

This Participant Information and Consent Form is # pages long. Please make sure you have all the pages.

1. Your Consent

You are invited to take part in this research project.

If this is a follow-on study, state this.

This Participant Information contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Participant Information carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend or your local health worker. Feel free to do this.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Participant Information and Consent Form to keep as a record.

2. Purpose and Background

The purpose of this project is

[State the aims of the project. Include the background and justification for the study, i.e. the rationale for the drug or device being trialed. In addition, clearly state if any standard treatment is being withheld as a consequence of participation, i.e. is participation in the research project an alternative to other standard treatments for the patient's condition/disease, or is it because standard treatment has not been successful for the patient's condition?]

In providing a statement of the aims of the project, it is preferable to describe this in objective terms by reference to the disease/condition, rather than in the subjective sense, as there may be no actual benefit to individual patients and the only possible benefit is long-term.

Include a statement of the current registration status in Australia, e.g. whether the drug/device has been approved for marketing in Australia.

Include a comparison with other drugs or devices currently used for the same purposes.]

A total of [number] people will participate in this project.

Previous experience has shown that [provide a brief summary – one or two sentences – of the literature review, the justification for the project and the context of the study, e.g. previous experience, summary of earlier studies and results.]

You are invited to participate in this research project because [state why the participant's involvement is sought/desirable]

This study is being sponsored by [name of Australian sponsor].

Insert information regarding sponsorship as appropriate.

Note: A distinction exists between formal sponsorship, for the purposes of the CTN application, and Commercial Sponsorship, for the purposes of legal indemnity for the institution and HREC. As a general rule, where the study is being Commercially Sponsored, an indemnity is required from an Australian corporate entity. This can be either an Australian related/subsidiary corporation of the international company, or, if none exists, the local corporate research organisation that is conducting the research project in Australia for the international pharmaceutical /device company.

Where there is also an Australian company involved, add: In order to conduct the study in Australia, there is a locally based corporate sponsor, [name].

Where no Commercial Sponsorship is available: This study is being conducted internationally by [name of international pharmaceutical company or collaborative research group].

Alternatively, where the research project is investigator-initiated, include the following:

This trial has been initiated by the investigator, Dr/Prof [name].

Note – in those situations where the parent company is not an Australian company any reference to “the Sponsor” in the Participant Information and Consent Form must name the Australian entity and not the international company.

If the research is for the purpose of obtaining a degree or other educational qualification, please state this here, e.g. The results of this research may be used to help researcher [name of researcher] to obtain a degree.

3. Procedures

Participation in this project will involve:

State:

- *The nature, number, timing and time commitment of all procedures*
- *Indicate and describe the nature of those tests or procedures that are in addition to those ordinarily performed as part of the routine care for patients with this condition/disease*
- *Indicate duration of patient's participation*
- *Explain and describe randomisation procedures, if applicable*
- *Explain the use of controls, if applicable, including the use of placebos and their purpose. State whether, if allocated to the placebo arm of the study, patients will not receive any treatment for their condition/disease, or whether they will still receive standard treatment.*
- *Quantify the participant's commitment where possible, e.g. an interview of half an hour, a tablespoon of blood, use of audio or videotapes, etc*

It is advisable to include a statement noting that continual review and monitoring will take place, regarding the efficiency and safety of the research project, and this will enable early detection of any problems patients may suffer. In the case of medical device trials, information should be provided about the mechanisms in place to track participants for the lifetime of the device, to detect any relevant adverse events and enable remedial action if a significant defect is detected.

4. Collection of Tissue Samples for Research Purposes

Specific consent is required from participants as to the taking, storage and later testing and analysis of tissue samples, including genetic tests. Therefore, where appropriate, the following sentence should be included:

By consenting to take part in this study, you also consent to the collection, storage and use of tissue samples as specified below.

However, if the study contemplates a separate and optional arm for tissue/genetic testing, then replace previous sentence with the following:

Participation in the tissue testing/genetic testing arm of this study is optional. If you agree to participate in this optional tissue testing/genetic testing arm of the study, please sign the separate Tissue Sample Consent Form attached.

The following information should be provided if tissue samples are to be taken and stored for further research:

- *The type and amount of tissue to be taken, as well as the bodily location that the tissue is to be taken from;*
- *The manner in which tissue will be taken and the safety and invasiveness of acquisition;*
- *The specific purpose for which tissue is to be taken, stored and used;*
- *Whether tissue samples will be identified, potentially identifiable or de-identified. If the samples are to be identified or potentially identifiable, include information as to the means by which the privacy/confidentiality of the stored tissue samples will be maintained;*
- *Clear information indicating the length of time for which tissue will be stored and whether/how tissue will be destroyed at the end of the Trial;*
- *Whether the research involves the establishment of a human tissue bank for future research use, the purpose of any contemplated future use, the means by which privacy/confidentiality of stored tissue samples will be maintained and the means by which future access by researchers will be controlled, e.g. the tissue will only be given to research projects approved by an HREC.*
- *The potential uses of the tissue, including any commercial uses*

Note regarding the waiver of future commercial rights/interests. From a legal and ethical perspective, it is questionable whether there is, in fact, any interest or right of an individual in their own cells/body parts. In this respect, any attempt to incorporate into the Participant Information a waiver by the participant of any future commercial rights or interests in the outcomes of the research from use of their tissue should be avoided.

Additional information to be included in the case of genetic tests:

- *Whether the study will have the capacity to provide information about an identifiable participant's future health or risk of having children with a genetic disorder, or information that may be relevant to the health of family members who are not a part of the study. If relatives are also to be approached, the researcher will need the consent of the research participant to do this, as well as information concerning the method of approach to relatives.*
- *Whether participants will be advised of project results and, if so, whether this will be grouped data or relate to individual participants and whether counselling will be provided;*
- *The potential for the research to detect/generate information of social significance, e.g. non-paternity or non-maternity, information that may influence access to insurance/employment;*
- *If it is found to be acceptable that no information concerning genetic disease predisposition is to be made available to research subjects, this should be clearly stated, noting all the implications;*
- *Information and counselling as to possible consequences of consenting to the use of genetic material;*
- *Participants should be informed that their views will be sought regarding the feedback of information of potential significance to their own or their relatives' future health;significance to their own or their relatives' future health;*

- Assurance that the participant's genetic material and information, where identified or potentially identifiable, will not be released for other uses without the participant's prior consent, unless required by law. Information should also be provided about the procedures to be followed in response to a request for access (e.g. requests by a donor, relative, other researchers, insurer, employer) to stored genetic material, or information generated by the research. If consent for future research use is declined, the genetic material and information should be disposed of after a specified period following completion of the research, (unless de-identified);
- If a genetic register is proposed, this should be established and conducted in accordance with the Guidelines for Genetic registers and Associated Genetic Material (NHMRC, 1999)

Additional requirements regarding HIV-Testing:

Under Victorian law, a medical practitioner is required to provide information about the medical and social consequences of being tested for HIV and possible results of such a test both before and after the conduct of such a test. Consequently, the Participant Information and Consent Form should be amended to clearly state that information and counselling will be provided in accordance with Victorian law, and the doctors involved in the Trial must comply in this regard. Suggested wording:

Information and counselling about the medical and social consequences of being tested for HIV and possible results of such a test will be provided both before and after the conduct of such a test in accordance with Victorian law.

Additional requirements regarding performance of autopsy:

A separate Consent Form must be provided to give express consent to the conduct of a post-mortem examination. The requirements for valid consent are as follows:

- *Express consent by the patient during their lifetime. This can be either written consent by the patient, or, where there is no written consent by the patient, oral consent by the patient, during his/her last illness, in the presence of two witnesses;*
- *Where there is no expressed consent by the patient during their lifetime, consent by the "senior available next of kin", defined to include, in the case of an adult, the deceased's spouse, son or daughter over the age of 18, parent, or in the event of none of the above being available, brother or sister over the age of 18 years.*

Note: The conduct of a post-mortem examination is NOT authorised if there is reason to believe that the deceased had, at any time, expressed an objection to the conduct of a post-mortem, either in writing or at any time during his/her last illness, orally in the presence of two witnesses.

5. Possible Benefits

Possible benefits include [describe any likely benefits to participants or other people in the future. If the significant benefits from the Trial are to accrue to members of society in the future and NOT the individuals taking part in the Trial, this should be made clear.]

If applicable, include a statement to the effect that: We cannot guarantee or promise that you will receive any benefits from this project.

6. Possible Risks

Possible risks, side effects and discomforts include [list and quantify all risks and discomforts involved in participating in the clinical trial, including possible adverse effects on physical health as well as emotional, economic and other types of disadvantage. This should include not only those relevant to the study drug/device but also those relevant to any tests or procedures participants will be required to undergo, as well as changes to existing therapies. Also, quantify all risks, for example, one in fifty.

Where possible, risks should also be put in the context of everyday events, for example, compared to the risk of death in a car accident.]

Include any risks in relation to the use of DNA techniques, toxins, mutagens, teratogens and carcinogens.

Participants must be clearly informed whether participation in the research study involves exposure to radiation. All research projects involving the use of ionising radiation, (even if this is part of standard treatment) must be referred to the Radiation Officer Safety of the institution where the ionising radiation will be administered. Researchers should refer to Module 5 Guidelines and must consult with the Radiation Safety Officer (RSO) at the institution where the ionising radiation treatment will occur.

The RSO will provide any special wording for the Participant Information and Consent Form and any radiation-related approvals.

Include a general statement advising that participants can suspend or even end their participation in the project if distress occurs. Information should be provided as to the mechanisms in place during the conduct of the study to monitor/identify and address any possible side effects.

Include psychological as well as physical risks.

If adverse reactions during interviewing are possible, ensure trained counselling is available. Make clear how the person can gain access to this counselling.

If applicable, include a warning or exclusion statement about conception, pregnancy and breast feeding, for example:

The effects of [insert name of trial drug] on the unborn child and on the newborn baby are not known. Because of this, it is important that study participants are not pregnant or breast-feeding and do not become pregnant during the course of the study. You must not participate in the study if you are pregnant or trying to become pregnant, or breast-feeding.

If you are male, you should not father a child. If you are female and child bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the study. Both male and female participants are strongly advised to use effective contraception during the course of the study and for a period of [insert period] months after completion of the study. You should discuss methods of effective contraception with your doctor. If you do become pregnant whilst participating in the study you should advise your treating doctor immediately. He/she will withdraw you from the study and advise on further medical attention should this be necessary. You must not continue in the study if you become pregnant. [Please remember to adapt this clause if study is specifically for female or male patients only and check for any site-specific requirements in relation to this statement.]

Where applicable, insert the following:

Chemotherapy may cause temporary or permanent sterility. Please discuss this with your doctor if you have any concerns about future fertility.

There may be additional unforeseen or unknown risks.

7. Other Treatments Whilst on Study

It is important to tell your doctor and the research staff about any treatments or medications you may be taking, including non-prescription medications, vitamins or herbal remedies and any changes to these during your participation in the study.

8. Alternatives to Participation

Alternative procedures/alternative treatments include [Describe appropriate alternative procedures or treatment that might be advantageous to the participant, if any. Describe standard treatment and its effectiveness and indicate how the research project differs from standard treatment. Include any disadvantages from withholding standard treatment. If there is no alternative treatment, state this.]

9. Privacy, Confidentiality and Disclosure of Information

[Information should be provided generally on plans by the researchers for the storage and disposal of data, whether the data is identified, identifiable or de-identified, where the data will be kept and who will have access to it, how long it will be stored and what will happen to the data at the end of the storage period.]

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. *[If additional use of the information is contemplated, this should be explained and specific consent sought from the participants for that additional use.]* It will only be disclosed with your permission, except as required by law. If you give us your permission by signing the Consent Form, we plan to *[discuss or publish]* the results with *[X or Y to Z]*.

If relevant, provide information regarding the review of health records by researchers and by representative of regulatory authorities and the Sponsor for the purpose of verifying the procedures and the data. For example:

Your health records and any information obtained during the study are subject to inspection (for the purpose of verifying the procedures and the data) by the Food and Drug Administration (FDA) of the United States of America (USA), other national drug regulatory authorities such as the Australian Government's Therapeutic Goods Administration (TGA) *[where this is applicable]* and authorised representatives of the Sponsor, *[sponsors name]* or as required by law. *[If the study involves both an international and an Australian sponsor, insert the names of both in this section.]* By signing the attached Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

If there will be commercial development of the research results, this should be stated.

In any publication, information will be provided in such a way that you cannot be identified. *[Describe how confidentiality will be maintained. Research involving focus groups presents special problems – you need to describe in detail the process of maximising confidentiality and protection of privacy in these situations.]*

Where it is considered desirable that a participant's general practitioner be informed of their decision to participate in a research project, the following additional sentence should be included:

It is desirable that your family doctor, *[General Practitioner's name]*, be advised of your decision to participate in this research project. By signing the Consent Form, you agree to your family doctor being notified of your decision to participate in this research project.

10. New Information Arising During the Project

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation.

In all cases, you will be offered all available care to suit your needs and medical condition.

11. Results of Project

[State how participants will be informed of the results when the research project is completed.]

12. Further Information or Any Problems

If you require further information or if you have any problems concerning this project (for example, any side effects), you can contact the principal researcher or *[list other appropriate persons involved in the project]*. The researchers responsible for this project are *[list names and contact phone numbers, including after hours number(s)]*.

13. Other Issues

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact

Name:

Position:

Telephone:

You will need to tell *[name]* the name of one of the researchers *[name]* given in section 12 above.

[Note: The contact person nominated should be someone independent of the research project.]

14. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with *[the Institution]*.

[Participants should also be told whether they are able to have their tissue samples or data withdrawn from the research project if they wish to do so, or whether there are restrictions on the withdrawal of samples or data.]

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing.

15. Reimbursement for your costs

You will not be paid for your participation in this trial. However, you will be reimbursed for any of the following costs that you incur as a result of participating in this trial *[give specific amount for specific items e.g. \$30 for taxi fares each visit]*

16. Ethical Guidelines

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of this Institution *[or name the HREC if it is not the HREC of this Institution]*.

[Where relevant, state that approval has been given by the Institution where research will be carried out (for example, School or day care centre) or by the Institution responsible for supervising the standard of care where the research will be carried out (for example, Department of Education).]

17. Injury

In the event that you suffer an injury as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to you.

If the study involves private patients, the following wording may be used in respect of those patients:

In the unlikely event that you suffer an injury as a result of participating in this trial, hospital care and treatment will be provided by the public health service at no extra cost to you **if you elect to be treated as a public patient at the public health service.**

For Commercially Sponsored clinical trials include the following:

18. Compensation

The Sponsor *[name of sponsor]* has agreed to provide compensation to you for any injury suffered as a result of your participation in the research project, in accordance with the Medicines Australia Guidelines for compensation for injury resulting from participating in a company-sponsored research project. A copy of the Medicines Australia Guidelines is available to you from the research staff on request.

19. Termination of the Study

This research project may be stopped for a variety of reasons. These may include reasons such as: unacceptable side effects, the drug being shown not to be effective, the drug being shown to work and not need further investigation and decisions made in the commercial interests of the Sponsor. *[Note - the reference to the Sponsor's interests should be omitted where the Trial is initiated by the investigator(s)]*

[Include a statement indicating whether there will be ongoing access to the study drug if the research project is terminated.]

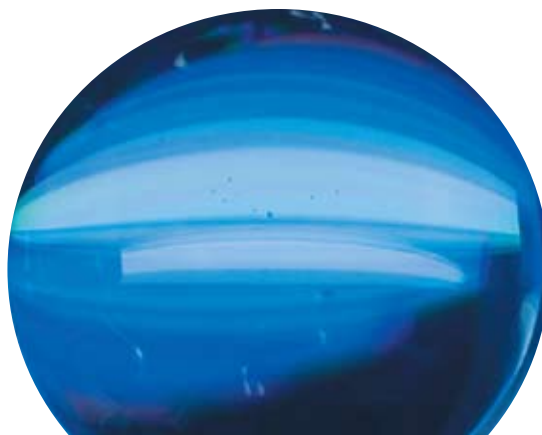
Copy to here ^

Notes for Researchers

Each page of the Participant Information and Consent Form must be numbered using the format page x of y and include a site name, date and version number.

Please check with the relevant HREC for any site-specific requirements and standard wording for Participant Information, for example, a clause concerning risks of pregnancy while participating in a research project, compensation statements for clinical trials, etc.

For participants aged less than 18 years, please provide the Participant Information in words that will be understood by the age group



● Template A

Consent Form

(Attach to Participant Information)

On Institution's Letterhead or Name of Institution

Consent Form

Version: _____

Dated: _____

Site: _____

Full Project Title: _____

I have read, or have had read to me in my first language, and I understand the Participant Information version x dated x.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this project according to the conditions in the Participant Information.

I have a copy of the Participant Information and Consent Form to keep.

I understand that the researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

Participant's Name (printed): _____

Signature: _____

Date: _____

Name of Witness to Participant's Signature (printed): _____

Signature: _____

Date: _____

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's Name (printed): _____

Signature: _____

Date: _____

* A senior member of the research team must provide the explanation and provision of information concerning the research project.

Note: All parties signing the Consent Form must date their own signature.

● Template B

Consent Form For Tissue Sample Storage And Use

(Attach to Participant Information)

If there is an option for tissue samples to be taken and stored for further research, it is suggested that consent to the use and storage of tissue be separate from the general consent to participate in the study. This is because it is often the case that participation in the testing and further storage of tissue is contemplated as a separate and alternative option for the patient. If separate Consent Forms are used, participants can still consent to the main study but not the additional tissue/genetic testing component.

On Institution's Letterhead or Name of Institution

Consent Form for Tissue Sample Storage and Use

Version: _____

Dated: _____

Site: _____

Full Project Title: _____

I consent to the storage and use of blood and tissue samples taken from me for use in further research as described in this Participant Information by *[insert name of researcher]*.

If appropriate, include the following statement:

By signing this Consent Form, I agree to the use of my tissue samples for genetic testing as outlined in the participant information.

If the study contemplates the use of tissue samples obtained from previous surgery/procedures, a separate specific consent should be obtained for this additional use of tissues previously taken and stored. In this situation, include the following statement:

By signing this Consent Form, I agree to the use of tissue samples obtained previously from my *[routine biopsy or surgery]* for the purposes of additional testing for *[state test to be performed on tissue(s)]*.

Participant's Name (printed): _____

Signature: _____

Date: _____

Name of Witness to Participant's Signature (printed): _____

Signature: _____

Date: _____

Researcher's name: _____

Signature: _____

Date: _____

Note: All parties signing the Consent Form must date their own signature.

● Template C

Third Party Consent Form (To be used by parents/guardians of minor children).

(Attach to Participant Information)

On Institution's Letterhead or Name of Institution

Third Party Consent Form

Version: _____

Dated: _____

Site: _____

Full Project Title: _____

I have read, or have had read to me in my first language, and I understand the Participant Information version x dated x.

I give my permission for *[participant's name]* to participate in this project according to the conditions in the Participant Information.

I will be given a copy of the Participant Information and Consent Form to keep.

The researcher has agreed not to reveal the participant's identity and personal details if information about this project is published or presented in any public form.

Participant's Name (printed): _____

Name of Person giving Consent (printed): _____

Relationship to Participant: _____

Signature: _____

Date: _____

Name of Witness to Parent/Guardian Signature (printed): _____

Signature: _____

Date: _____

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant's parent/guardian has understood that explanation.

Researcher's Name (printed): _____

Signature: _____

Date: _____

* A senior member of the research team must provide the explanation and provision of information concerning the research project.

Note: All parties signing the Consent Form must date their own signature.

● Template D

Person Responsible Consent Form (To be used for participants who are involved in a medical research procedure and who lack the capacity to consent for themselves.)

(Attach to Participant Information)

On Institution's Letterhead or Name of Institution

Person Responsible Consent Form

Version:

Dated:

Site:

Full Project Title:

I have read, or have had read to me in my first language *[only include this phrase if the documents will be translated into other languages]*, and I understand the Participant Information version x dated x.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I am the person responsible (as defined in the *Guardianship and Administration Act 1986 (Vic)*) of *[participant's name]*. I consent to the participation *[OR ongoing participation]* of *[participant's name]* in the research project named above, according to the conditions in the Participant Information.

I believe the carrying out of the procedure is not contrary to the best interests of *[participant's name]*.

I will be given a copy of the Person Responsible Information and Consent Form to keep.

The researcher has agreed not to reveal *[participant's name]'s* identity and personal details if information about this project is published or presented in any public form.

Participant's Name (printed):

Name of Person providing consent (printed):

Relationship to participant:

Signature:

Date:

Witness to Signature (printed):

Signature:

Date:

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the person named above as the person responsible has understood that explanation.

Researcher's Name (printed):

Signature:

Date:

* A senior member of the research team must provide the explanation and provision of information concerning the research project.

Note: All parties signing the Consent Form must date their own signature.

● Template E

Revocation of Consent Form (To be used for participants who wish to withdraw from the project.) (Attach to Participant Information)

On Institution's Letterhead

Revocation of Consent Form

Full Project Title:

I hereby wish to WITHDRAW my consent to participate in the research proposal named above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with Name of Institution.

Participant's Name (printed):

Signature:

Date:

● Attachment D

Adverse Events Report Form

Project No:

Project Title:

Principal Investigator:

Institution:

Date of Original Approval:

1. Describe the adverse event

2. Indicate how the adverse event relates to the project

3. Summarise any ethical issues raised by the occurrence of this adverse event

4. Relationship of adverse event to study drug/device

Event/report No: Unrelated Possibly related Probably related Definitely related

5. Are there any implications for the project protocol or Participant Information and Consent Forms?

6. Has the Commercial Sponsor been notified in accordance with the terms of indemnity

7. Recommended Action:

- Change to the protocol Y / N
- Change to the Plain Language Statement Y / N
- Previously Enrolled Participants to be notified Y / N
- The study to be stopped Y / N
- No action Y / N

Principal Investigators Signature

Date:

Human Research Ethics Committee Recommendations

Date:



Level 30, 35 Collins Street
Melbourne VIC 3000

PO Box 18409
Collins Street East, VIC 8003

Telephone: 03 9270 6900
Facsimile: 03 9270 6918
E-mail: office@vmia.vic.gov.au