CLINICAL TRIAL AGREEMENTS AND INSURANCE GUIDELINES FOR UNSW STAFF

Version 1.0 – May 2011

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1. INTRODUCTION

This document provides general information on the legal and insurance arrangements relating to the conduct of clinical trials at UNSW by UNSW staff. It is intended as a guide only for UNSW staff and it should not be made available to any external organisation.

2. BACKGROUND

2.1 Definition of a clinical trial

According to the *National Statement on Ethical Conduct in Human Research* (2007) a clinical trial is a form of human research designed to find out the effects of an intervention, including a treatment or diagnostic procedure. A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedures and devices, a preventive procedure, or a diagnostic device or procedure.

2.2 Responsibilities of the trial sponsor

The sponsor of a 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.

The general responsibilities of the trial sponsor are set out in the *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)*. The sponsor responsibilities include obtaining ethical approval for the trial, obtaining and maintaining adequate insurance cover for the trial, notifying the Therapeutic Goods Administration of the trial (if required) and implementing suitable agreements with each participating site.

It is very common for a pharmaceutical company to act as the trial sponsor. If the trial is investigator-initiated and funded by UNSW (e.g. using NHMRC awarded funds or other such grant funding), UNSW may act as the sponsor.

2.3 Role of the Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) is the Australian regulatory authority responsible for clinical trials of drugs and devices conducted in Australia. Where a trial or study involves the testing of any drug or device not entered on the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration, as well as the use of marketed drugs and devices that extends beyond the conditions of existing marketing approval, then the trial must be notified to the TGA and conducted under the Clinical Trial Exemption Scheme (CTX) or Clinical Trial Notification Scheme (CTN). This includes trials or studies involving new indications extending the use of a product to a new population group, as well as the extension of doses, or duration of treatments, outside the approved range.

3. CLINICAL TRIAL RESEARCH AGREEMENTS

The sponsor of a trial must enter into a clinical trial research agreement (CTRA) with each site documenting the obligations of each party with respect to the conduct of the trial and outlining any payments that will be made to the site.

A number of template CTRA's have been developed through a collaboration between the Victorian Managed Insurance Authority, state health departments and industry. These templates are widely used within Australia and provide a uniformly accepted set of terms so the agreements can be prepared and executed without the need for substantial review.

These templates are the preferred templates for use in all NSW public hospitals.

3.1 Which template CTRA should I use?

The three main templates are available via the Medicines Australia website:
http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/

3.1.1 Collaborative OR Cooperative Research Group (CRG) template

This template should be used when a collaborative or cooperative group (CRG) acts as the sponsor of a trial. A CRG is defined as 'an academic and/or non-commercial collaborative research group'. This template should be used to contract with sites when UNSW initiates and sponsors a trial or acts as the local sponsor for a non-commercial consortium.

3.1.2 Commercially Sponsored Trials template

This template is for use by a commercial sponsor (e.g. an Australian pharmaceutical company or Australian subsidiary of an international pharmaceutical company) only. UNSW may receive this agreement from a commercial sponsor. It should not be issued by UNSW for any UNSW sponsored trials.

3.1.3 Contract Research Organisation (CRO) template

This template is for use by a contract research organisation (CRO) engaged to act as the local sponsor of a clinical trial by an international commercial sponsor who is the owner of the investigational product. UNSW may receive this agreement from a CRO but it would not normally be issued by UNSW to a site.

3.2 Can I use these templates for trials of medical devices?

The Medical Technology Association of Australia has developed a separate CTRA suitable for trials of medical technologies. The template can be found here:
http://www.mtaa.org.au/pages/page283.asp

3.3 Can I use these templates for overseas sites?

The template CTRA's found on the Medicines Australia website are not generally suitable for use with international sites. UNSW has developed a separate CTRA for use in such instances. Please contact the Legal Office (Research) to obtain a copy of this template.

3.4 How do I complete the template CTRA?

3.4.1 UNSW sponsored trial

- Download the most current CRG template from the Medicines Australia website (http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/);
- Complete the front page and schedules as per the template instructions (or refer to the example appearing at Attachment 1 for additional guidance) to create an agreement for each site.

If you are using the Legal Office (Research) template for overseas sites, insert the party and trial information on page 1 and complete the Schedules in a similar fashion as you would the above templates.

Do not amend any other section of the template agreement.

3.4.2 Pharma sponsored trial

It is the responsibility of the trial sponsor to issue a suitable agreement to UNSW. Where UNSW is being engaged to act as a site in a pharma sponsored trial, the Medicines Australia templates must be used and the "Institution" must be noted as "**The University of New South Wales**".

3.5 Can the terms of the CTRA be amended?

The main body of the template agreements cannot be amended. The Special Conditions schedule should be used to identify any clauses that need to be added, deleted or amended.

If UNSW is the trial sponsor and the trial is governed by one or more existing agreements (e.g. such as a grant or drug supply agreement), UNSW may need to insert special conditions to ensure that each site conducts the trial in accordance with the terms of those existing agreements.

If you think Special Conditions may need to be added for a UNSW sponsored trial, or if Special Conditions have been proposed by an external sponsor, the agreement should undergo a legal review prior to signature by UNSW. Please send the draft agreement to the UNSW Grants Management Office with background information and a request for legal review.

3.6 How do I get the CTRA executed?

3.6.1 No special conditions or special conditions pre-approved

If the appropriate template has been used and populated (as per these guidelines) and **no special conditions have been proposed**, or if the special conditions have been reviewed and pre-approved by the Legal Office (Research):

Submit the agreement in duplicate (or triplicate, if required) to the Grants Management Office for signature on behalf of UNSW with a covering note confirming that the agreement does not require legal review.

3.6.2 Special conditions requiring review

If the appropriate template has been used and populated (as per these guidelines) and **special conditions have been proposed** by an external sponsor or need to be inserted by UNSW (as sponsor):

Submit an electronic copy of the CTRA to the Grants Management Office with a request for legal review. The Legal Office (Research) will arrange signature following review or will advise you to submit the agreements to the Grants Management Office as per the above.

Once signed by UNSW, the executed agreement will be returned in accordance with any accompanying instructions. If the agreement is fully executed, one original can be retained by the site and one by the sponsor. The UNSW original should be retained by the School/Centre and a copy should be sent to the Grants Management Office.

3.7 Can the CTRA be varied once signed?

Yes, the agreement can be varied. For UNSW sponsored trials an existing CTRA can be varied using a template variation developed by the Legal Office (Research). Please contact the Legal Office (Research) with an outline of your requirements and a copy of the original CTRA to be amended so a suitable variation can be prepared.

Variation agreement(s) can be submitted to the Grants Management Office for execution as per the instructions above for CTRA agreements.

3.8 Can the CTRA be varied to add a sub-study?

Yes, but only in some instances. If the sub-study is incorporated into the original (main study) protocol, the main study CTRA can be varied to incorporate the sub-study. If the sub-study is the subject of a separate protocol, a new CTRA must be implemented. Seek advice from the Legal Office (Research) if you are unsure. An example variation can be found at Attachment 3.

4. INDEMNITY

Commercial sponsors are required to indemnify each site in a form no less favourable than the current Medicines Australia Form of Indemnity for Clinical Trials.

Whilst UNSW is a non-commercial organisation, if UNSW sponsors/initiates a clinical trial involving patients and/or employees of another organisation (one or more), including an affiliated teaching hospital, UNSW will generally provide (and be expected to provide) that organisation with an indemnity using the Medicines Australia Form of Indemnity for Clinical Trials.

4.1 Medicines Australia form of indemnity

The template form of indemnity developed by Medicines Australia is an adaptation of the form used by the Association of the British Pharmaceutical Industry (ABPI), for use in Australia. It is 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 also encouraged to use the form.

Having a preferred form of indemnity ensures that the indemnity agreements can be prepared quickly and executed by the University without the need for review.

The Medicines Australia form of indemnity is currently the recommended form within Australia and is also used by UNSW when indemnifying overseas sites (unless the overseas site has their own preferred form).

The templates can be found here:
http://medicinesaustralia.com.au/issues-information/clinical-trials/indemity-and-compensation-guidelines/

There are currently two template forms to be used as follows:

4.1.1 Standard

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

4.1.2 HREC Review Only

For use when the Indemnified Party is providing HREC review only of the Study.

4.2 How do I complete the form of indemnity?

4.2.1 UNSW sponsored trial

To complete the indemnity:

- Download the appropriate template from the Medicines Australia website (http://medicinesaustralia.com.au/issues-information/clinical-trials/indemity-and-compensation-guidelines/);

- Insert the relevant party and study details in the top part of the document (bold section). Be sure to insert the correct legal name (not a trading name), ABN (for sites within Australia) and address of each party.
- In paragraph 1, select the patient type and insert the site investigator(s) names, as required.

Refer to the example indemnity at Attachment 2 for additional guidance.

If the trial is likely to include a number of sub-studies, you may also like to include the following text after the study name: "*and any related sub-studies that the Indemnified Party participates in.*" to ensure that the indemnity extends to include these sub-studies.

Do not amend any other section of the template agreement.

4.2.2 Pharma sponsored trial

It is the responsibility of the trial sponsor to issue an indemnity to UNSW. The Medicines Australia form of indemnity must be used and the "Indemnified Party" must be noted as "**The University of New South Wales**".

4.3 How do I get the indemnity executed?

If the appropriate template has been used and populated (as per these guidelines):

Submit the final agreement in duplicate (or triplicate, if required) to the UNSW Grants Management Office for signature by UNSW along with a covering note confirming that the template terms are unamended.

Once signed by UNSW, the executed agreement will be returned in accordance with any accompanying instructions. If the agreement is fully executed, one original can be retained by the site and one by the sponsor. The UNSW original should be retained by the School/Centre and a copy should be sent to the Grants Management Office.

5. IMPORTANT ISSUES TO CONSIDER WHEN CONTRACTING

5.1 Correctly identifying the contracting parties

Organisations entering into contracts must be legal entities. It is also important to ensure that the entities identified in the agreement are capable of and intend to perform the stated responsibilities – i.e. that the appropriate legal entities have been identified.

The parties must be identified by their legal title (including ABN/ACN), registered address and business name. The legal name for UNSW should be stated as:

The University of New South Wales
or

The University of New South Wales, ABN 57 195 873 179, a body corporate established pursuant to the *University of New South Wales Act 1989* (NSW), of UNSW Sydney NSW 2052 Australia

Internal administrative units of UNSW such as faculties, schools and departments generally do not have independent legal status and should not be listed as parties to an agreement.

With respect to the non-UNSW party - it is recommended that you independently verify the legal name and entity type for that party by doing a free ASIC search (http://www.asic.gov.au/asic/asic.nsf).

You can also verify certain company details via the Australian Business Register (http://www.abr.business.gov.au/(1ymj1avrt2oph0mr31zp4g55)/main.aspx).

A list of commonly contracted sites and their correct legal names can be found at Attachment 4.

5.2 Related agreements (UNSW sponsored trials)

If UNSW is the trial sponsor and UNSW has entered into any other agreements relating to the trial (e.g. a grant or funding agreement, drug supply agreement or non-disclosure agreement), you should seek advice from the Legal Office (Research) before implementing any CTRA's by submitting a request for legal review through the Grants Management Office.

The Legal Office (Research) may advise you to include special conditions in the CTRA to ensure that each site agrees to conduct the trial in accordance with any additional terms reflected in the other agreement/s and does not cause UNSW to be in breach of those additional terms.

5.3 Special arrangements for NHMRC funded trials

If your project is being conducted with the use of NHMRC funds please seek advice from the Grants Management Office or Legal Office (Research) before implementing any multi-institutional or clinical trial agreements relating to the distribution of funds to site investigators or collaborating organisations. The Grants Management Office / Legal Office (Research) will need to analyse your specific project requirements in order to recommend appropriate legal arrangements.

5.4 Hospital involvement and clinical academics

If you are a clinical academic and wish to conduct the clinical trial wholly through the hospital with no use of UNSW staff or resources or use of UNSW's name, the agreements should be between the hospital (or Local Health Network) and the relevant study sponsor.

If you are a clinical academic and plan to conduct the clinical trial through your university appointment but wish to use hospital resources and/or access hospital patients, you should bring this to the attention of the Grants Management Office and hospital governance office. If the study is a UNSW sponsored (investigator initiated) study, UNSW will provide the hospital with a CTRA and indemnity as required. If the study is a pharma sponsored study, a decision to implement separate agreements governing the hospital's involvement is matter for hospital governance office to advise.

5.5 Authority to sign

It is important to ensure that the agreements are signed by a duly authorised representative of each party. In the case of UNSW, the authorised representative is usually the Director of the Grants Management Office.

6. INSURANCE

The sponsor of a trial is required to maintain an adequate level of insurance for legal liability to pay damages or compensation as a result of any claim or claims made by research subjects for bodily injury caused by any act, error or omission in connection with clinical trials.

UNSW maintains insurance cover for its liabilities in relation to the conduct of clinical trials by UNSW staff. UNSW insurance provides cover for trials where UNSW personnel are involved and where the trial protocol has been approved or ratified by the UNSW Human Research Ethics Committee.

6.1 Evidence of insurance

Where UNSW is the sponsor of a trial, the sites and site HREC's will generally require evidence of this insurance. Evidence of UNSW insurance (certificates of currency) can be obtained from the UNSW Risk Management Unit.

Where UNSW is involved in externally sponsored trials, UNSW should always request and be provided with evidence of the sponsors insurance before executing any trial agreements.

6.2 Other insurance

Non-UNSW personnel involved in the conduct of a trial should also have adequate insurance cover in relation to their own negligent or wrongful acts or omissions or breaches of statutory duties.

Research carried out by NSW public health system personnel is generally covered by the NSW Government's self insurance scheme, the Treasury Managed Fund (TMF) although the extent of this cover may vary for Staff Specialists and Visiting Medical Officers and would need to be confirmed on a case by case basis.

Registered medical practitioners are required by law to maintain (at their own cost) membership of a Medical Defence Organisation and be fully insured for their own malpractice, professional errors, omissions or negligence. Some policies require the practitioner to notify their insurer of specific research involvement before the cover applies.

6.3 Overseas sites and insurance

If the trial is being conducted with the involvement of overseas sites, it is recommended that you provide a list of the overseas sites involved in the trial to the UNSW Risk Management Unit prior to implementing any agreements to request confirmation that UNSW's clinical trials insurance will extend to cover the trial activities at all such sites.

For more information on the insurance arrangements for clinical trials or for copies of UNSW's insurance certificates please contact the UNSW Risk Management Unit.

7. CONTACTS, REFERENCES AND LINKS

Useful contacts:

UNSW Grants Management Office
http://www.gmo.unsw.edu.au/

UNSW Legal Office (Research)
http://www.legal.unsw.edu.au/research/index.html

UNSW Risk Management
http://www.fin.unsw.edu.au/RiskManagement/RiskManagement.html

Reference information:

National Statement on Ethical Conduct in Human Research (2007)
http://www.nhmrc.gov.au/publications/ethics/2007_humans/section3.3.htm#d

Australian Code for the Responsible Conduct of Research
http://www.nhmrc.gov.au/publications/synopses/r39syn.htm

The Australian Clinical Trial Handbook - A simple, practical guide to the conduct of clinical trials to International standards of Good Clinical Practice (GCP) in the Australian context
http://www.tga.gov.au/industry/clinical-trials-handbook.htm

Access to Unapproved Therapeutic Goods – Clinical Trials in Australia - describes the regulations for allowing patients access to unapproved medicines or medical devices by participation in a clinical trial
http://www.tga.gov.au/industry/clinical-trials-guidelines.htm

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - an internationally accepted standard for the designing, conducting, recording and reporting of clinical trials.
http://www.tga.gov.au/industry/clinical-trials-note-ich13595.htm
(Annotated with TGA comments)

NSW Health Policy Directives

Clinical Academics Employed in the NSW Health Service
http://www.health.nsw.gov.au/policies/pd/2010/PD2010_036.html

Clinical Trial Research Agreement for Public Health Organisations (Commercial Entities)
http://www.health.nsw.gov.au/policies/pd/2009/PD2009_033.html

Clinical Trial Research Agreement Public Health Orgs (Collaborative or Cooperative Research Groups)
http://www.health.nsw.gov.au/policies/pd/2009/PD2009_032.html

Clinical Trials - Insurance and Indemnity
http://www.health.nsw.gov.au/policies/pd/2011/PD2011_006.html

Other useful links:

National Health and Medical Research Council (NHMRC)
http://www.nhmrc.gov.au/health_ethics/human/trials.htm

Therapeutic Goods Administration – includes access to CTN/CTX forms
http://www.tga.gov.au/hp/clinical-trials.htm

Medicines Australia – includes access to template Clinical Trial Research Agreements and standard form Indemnities
http://medicinesaustralia.com.au/issues-information/clinical-trials/

Medical Technology Association of Australia
http://www.mtaa.org.au/pages/page283.asp

Victorian Managed Insurance Authority
http://www.vmia.vic.gov.au/Risk-Management/Clinical-trials.aspx

Australian LifeScientist article – "Top 10 clinical trial mistakes"
http://www.lifescientist.com.au/article/322080/special_feature_top_10_clinical_trial_mistakes/

ATTACHMENT 1

Example Collaborative Research Group CTRA (UNSW as sponsor)

Clinical Trial Agreement

Collaborative or Cooperative Research Group (CRG) Studies – Standard Form

The body of this Standard Form Agreement should not be amended. Any proposed changes to this Agreement must be incorporated into **Schedule 4** by way of Special Conditions.

Details of the parties

Institution:	*INSERT the full **legal name** of the site. This will often be different to the name by which the site is commonly known.* *If you are unsure of the legal name, request confirmation from the site and independently verify the details by doing a business search via the ASIC or the Australian Business Register websites:* http://www.asic.gov.au/asic/asic.nsf http://www.abr.business.gov.au/(1ymj1avrt2oph0mr31zp4g55)/main.aspx
Name:	*INSERT the legal name (as noted above) or trading name of the site*
Address:	*INSERT the registered address of the site*
ABN:	*INSERT the ABN for the site and confirm that the ABN belongs to the legal entity identified as the "Institution" above.*
Contact for	*INSERT a contact person for the site*

Notices:	
Fax for Notices:	
Phone Number:	

Name of CRG:	**The University of New South Wales**
Address:	**UNSW Sydney NSW 2052**
ABN:	**57 195 873 179**
Contact for Notices:	*INSERT a contact person for UNSW*
Fax for Notices:	
Phone Number:	

Study name:	*INSERT the full study title*
Protocol Number:	*INSERT the protocol number (or HREC number if no protocol number)*
Date of Agreement:	*Leave blank or insert "Date of last signature"*

[TERMS OF AGREEMENT INTENTIONALLY DELETED]

In witness hereof, the parties have caused this Agreement to be executed as of the Agreement Date below.

Signed on behalf of the **CRG**

Signed: *TO BE SIGNED by an authorised UNSW signatory – usually the Director of the Grants Management Office*

Name: _____

Position: _____

Date: _____

Signed on behalf of the **INSTITUTION**

Signed: *TO BE SIGNED by an authorised signatory on behalf of the site. Must be a site employee or representative and preferably not the site Principal Investigator (who should sign further below)*

Name: _____

Position: _____

Date: _____

The Principal Investigator acknowledges this Agreement and understands the obligations it imposes

Acknowledged by the **PRINCIPAL INVESTIGATOR**

Signed: *TO BE SIGNED by the site Principal Investigator (who should be a site employee but may also be a UNSW employee in the case of a conjoint.*

Name: _____

Position: _____

Date: _____

Schedule 2: Key Information

(to be inserted by CRG)

Study Name:	*INSERT the full study title*
Study Site/s:	*INSERT the name of the Institution's study site/s that will be involved in this trial*
Protocol Number:	
Target number of Study Subjects:	Minimum: Maximum:
Recruitment Period:	Start: / /
	End: / /
Principal Investigator Name:	*INSERT the name of the site Principal Investigator*
Address:	*INSERT the address for the site Principal Investigator*
	State: P/code:
Responsible HREC:	*INSERT the name of the HREC overseeing the conduct of the trial*
Equipment:	*INSERT details of any equipment to be provided to the site or insert "n/a"*

Investigational Product:	*INSERT details of the study drug / device to be provided to the site or insert "n/a"*

Schedule 3: Payments

Please Paste/Enter Text In Field Below

INSERT details of any payments that will be made to the site, including:

- *Breakdown of payments (per patient costs / one off payments)*
- *Invoicing schedule*
- *Information to be included with invoices*
- *UNSW address for invoices*
- *Site instructions relating to payments (if any)*

IF NO PAYMENTS ARE TO BE MADE TO THE SITE INSERT "No payments are to be made by the CRG to the Institution under this Agreement".

IF THE STUDY IS BEING CONDUCTED WITH THE USE OF NHMRC FUNDS AND THE INVESTIGATORS FROM THE SITE ARE NAMED PERSONNEL ON THE NHMRC APPLICATION please seek advice from the Grants Management Office or Legal Office (Research) in connection with the completion of this Schedule and the Agreement to ensure there is no duplication between this Agreement and any Multi-Institutional Agreement (MIA) that is required to be put in place for the grant. It is recommended that you also delay implementing the MIA until you have discussed all agreement requirements with the Grants Management Office or Legal Office (Research).

The terminology used in the schedule should be consistent with the rest of the agreement (e.g. when using the Medicines Australia CRG CTRA use "Institution" for the contracted party, "CRG" for UNSW and words such as "Study" and "Site" which are all defined terms described in the 'Definitions' section of the agreement.

Schedule 4: Study Protocol Identification

Full Title: *INSERT the full protocol title*

Version Number: *INSERT protocol version number*

Date: / /

List of Key attachments: *INSERT details of any key attachments*

Schedule 5: Special Conditions

Please Paste/Enter Text In Field Below

INSERT details of any special conditions to apply.

If UNSW is the trial sponsor, special conditions may arise from a related agreement between UNSW and a third party (such as a grant funding agreement or drug supply agreement). Please seek advice from the Legal Office (Research) if you are conducting a trial that is the subject of any third party agreement/s.

The terminology used in the schedule should be consistent with the rest of the agreement (e.g. when using the Medicines Australia CRG CTRA use "Institution" for the contracted party, "CRG" for UNSW and words such as "Study" and "Site" which are all defined terms described in the 'Definitions' section of the agreement.

ATTACHMENT 2

Example Standard Form of Indemnity (UNSW as sponsor)

MEDICINES AUSTRALIA FORM OF INDEMNITY FOR CLINICAL TRIALS
STANDARD

To: **<Insert Name, address and ABN number, if applicable, of the legal entity representing the site where the study will be conducted> ("the Indemnified Party")**

From: **The University of New South Wales, of UNSW SYDNEY NSW 2052, ABN 57 195 873 179 ("the Sponsor")**

Re: **Clinical Study No. <insert number>, <insert protocol title including name of product>**

1 The Indemnified Party agrees to participate in the above sponsored study ("the Study") involving <select appropriate option {patients of the Indemnified Party} {non-patient volunteers}> ("the Subjects") to be conducted by <insert 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 3

Example CTRA Variation (UNSW as sponsor)

Variation to the Clinical Trial Agreement

Details of the parties

Institution:	*INSERT the full **legal name** of the site. This will often be different to the name by which the site is commonly known.* *If you are unsure of the legal name, request confirmation from the site and independently verify the details by doing a business search via the ASIC or the Australian Business Register websites:* http://www.asic.gov.au/asic/asic.nsf http://www.abr.business.gov.au/(1ymj1avrt2oph0mr31zp4g55)/main.aspx
Name:	*INSERT the legal name (as noted above) or trading name of the site*
Address:	*INSERT the registered address of the site*
ABN:	*INSERT the ABN for the site and confirm that the ABN belongs to the legal entity identified as the "Institution" above.*
Contact for Notices:	*INSERT a contact person for the site*
Fax for Notices:	
Phone Number:	

Name of CRG:	**The University of New South Wales**
Address:	**UNSW Sydney NSW 2052**
ABN:	**57 195 873 179**
Contact for Notices:	*INSERT a contact person for UNSW*
Fax for Notices:	

Phone Number:	

Study name:	*INSERT the full study title*
Protocol Number:	*INSERT the protocol number (or HREC number if no protocol number)*
Variation Agreement Date:	*Leave blank or insert "Date of last signature"*

THIS VARIATION AGREEMENT IS MADE BETWEEN THE CRG AND INSTITUTION

RECITALS

A. The CRG is an academic and/or non-commercial collaborative research group responsible for sponsoring, initiating, managing, developing and coordinating the Study.

B. The Institution, through the Principal Investigator, is responsible for the conduct of the Study at the Study Site(s).

C. The CRG and Institution have entered into a Clinical Trial Agreement dated <insert date> governing their respective obligations in relation to the Study.

D. The parties wish to vary the Clinical Trial Agreement dated <insert date> to <insert brief description of reason for variation e.g. to allow for an additional patient visit / to include the conduct of a sub-study>.

OPERATIVE PROVISIONS

1. INTERPRETATION

1.1. The defined terms used in this Variation Agreement shall have the same meaning as given in the Clinical Trial Agreement.

2. VARIATION

2.1. Schedule 2 and 3 to the Clinical Trail Agreement are deleted and replaced with the revised Schedule 2 and 3 appearing below.

3. ENTIRE AGREEMENT

3.1. The Clinical Trial Agreement, as varied by this Variation Agreement, comprises the entire agreement between the parties and the Clinical Trial Agreement shall be read

and construed as one with this Variation Agreement and shall continue to be in force except as varied by this Variation Agreement.

In witness hereof, the parties have caused this Variation Agreement to be executed as of the Variation Agreement Date below.

Signed on behalf of the **CRG**

Signed: _____

Name: _____

Position: _____

Date: _____

Signed on behalf of the **INSTITUTION**

Signed: _____

Name: _____

Position: _____

Date: _____

The Principal Investigator acknowledges this Variation Agreement and understands the obligations it imposes

Acknowledged by the **PRINCIPAL INVESTIGATOR**

Signed: _____

Name: _____

Position: _____

Date: _____

Schedule 6: Payments

INSERT a complete replacement payment schedule incorporating the original payments for the study and any variations

Schedule 7: Study Protocol Identification

Full Title: _____

Version Number: _____

Date: ____/____/____

List of Key attachments: _____

ATTACHMENT 4

List of sites and their legal name

(Correct as of May 2011)

SITE NAME	ABN	LEGAL NAME
Aboriginal Medical Service - Western Sydney	ABN 82 174 391 271	Aboriginal Medical Service Western Sydney Co-operative Limited
AIDS Medical Unit	ABN 66 329 169 412	The State of Queensland acting through Queensland Health AIDS Medical Unit of (address).
Albion Street Centre	ABN 70 442 041 439	South Eastern Sydney Local Health Network
Alfred Hospital	27 318 956 319	Alfred Health
Asquith Medical Centre	ABN 68 336 471 010	Donald McKenzie Family Trust & J D Healey
Belmont Hospital	ABN 63 598 010 203	Hunter New England Local Health Network
Centre Clinic	ABN 52 907 644 835	The Victorian AIDS Council Inc.
Centre for Addiction Medicine	ABN 48 702 394 764	Western Sydney Local Health Network
Clinic 36 Outreach Clinic (Royal Prince Alfred Hospital)	ABN 52 521 556 358	Damson Software Pty Ltd & Zajodazac Limited
Cowra Medical Associates	ABN 37 926 491 092	The Trustee for CMA Services Unit Trust
Dr Doong's Surgery	ABN 96 070 618 388	Dr N C Doong
East Sydney Doctors	ABN 44 003 498 342	407 Doctors
Gateway and Woodlands Clinic	ABN 31 910 677 424	Nepean Blue Mountains Local Health Network
Hunter New England Pharmacotherapy Services	ABN 63 598 010 203	Hunter New England Local Health Network
Kireketon Road	ABN 70 442 041 439	South Eastern Sydney Local Health Network
Kite Street Community Health Centre	ABN 50 629 556 404	Western Sydney Local Health Network
Langton Centre	ABN 70 442 041 439	South Eastern Sydney Local Health Network
Liverpool Hospital	ABN 46 738 965 843	South Western Sydney Local Health Network
Lyell McEwin Hospital	ABN 96 269 526 412	Adelaide Health Service Inc.
Nepean Hospital	ABN 31 910 677 424	Nepean Blue Mountains Local Health Network
Northside Clinic	ABN 81 048 493 797	Northside Unit Trust
Prahran Market Clinic	ABN 91 150 177 031	Norman Julius Roth and Beng Hor Eu and Sven Strecker
Prince of Wales Hospital	ABN 70 442 041 439	South Eastern Sydney Local Health Network
Princess Alexandra Hospital	ABN 66 329 169 412	The State of Queensland acting through Queensland Health, Princess Alexandra Hospital, of (address).
Rankin Court	ABN 77 054 038 872	St Vincent's Hospital Sydney Limited
Regent House Outreach Clinic	ABN 58 001 433 245	Carmond (Nominees) Pty Ltd
Royal Adelaide Hospital	ABN 96 269 526 412	Adelaide Health Service Inc.
Royal Hospital for Women	ABN 70 442 041 439	South Eastern Sydney Local Health Network
Royal Melbourne Hospital	ABN 73 802 706 972	Melbourne Health
Royal North Shore Hospital	ABN 63 834 171 987	Northern Sydney Local Health Network
Royal Perth Hospital	ABN 13 993 250 709	The Minister for Health is incorporated as the board of Royal Perth Hospital under s7 of the Hospitals and Health Services Act 1927 (WA) and has delegated all the powers and duties as such to the Director General of Health

SITE NAME	ABN	LEGAL NAME
Royal Prince Alfred Hospital	ABN 17 520 269 052	Sydney Local Health Network
Royal South Sydney Hospital	ABN 70 442 041 439	South Eastern Sydney Local Health Network
St Geroge Hospital	ABN 70 442 041 439	South Eastern Sydney Local Health Network
St Vincent's Hospital	ABN 77 054 038 872	St Vincent's Hospital Sydney Limited
Sutherland Hospital	ABN 70 442 041 439	South Eastern Sydney Local Health Network
Sydney Hospital and Sydney Eye Hospital	ABN 70 442 041 439	South Eastern Sydney Local Health Network
Sydney Sexual Health Centre	ABN 70 442 041 439	South Eastern Sydney Local Health Network
Taylor Square Private Clinic	ABN 64 066 176 243	St Denis Pty Limited
The Byrne Surgery	ABN 75 446 160 021	Andrew James Byrne
The Queen Elizabeth Hospital	ABN 96 269 526 412	Adelaide Health Service Inc.
Westmead Hospital	ABN 48 702 394 764	Western Sydney Local Health Network