

SITE SPECIFIC DOCUMENTS New Trials

To be used in conjunction with the NEAF

(If you need word versions of these documents, please email –
ethics@austin.org.au)

1 Undertaking by Investigators Form

This must be signed by all investigators and included with the submission.

2 Lay Summary

A Lay Summary is a précis of the protocol in lay language. It is the method of communication between the investigator and the Human Research Ethics Committee members since they do not receive the full protocol. It should not be a cut and paste from the Participant Information and Consent Form.

3 Non Drug Study Cover Sheet

For all studies being submitted to the Non Drug Study Review Committee

4 Genetic Checklists

For studies involving any genetic component. Check List 3 to be added to PICF

5 Sign off forms from Departments:

- **Sign off from Pharmacy**
- **Sign off from Pathology**
- **Sign off from Radiology**
- **Sign off from Nuclear Medicine**
- **Sign off from PET Centre**
- **Sign off for Therapeutic Devices**
- **Health Information Services**

And Authorisation of payment for departmental services provided

6. Ethics/Governance Payment Form – new project and protocol amendment

7. Ethics Payment Form – Fast Track

8. Clinical Trial Agreement – cover page

Only submit the relevant documents with your application

Undertaking by Investigators

Project Title:

I/We, the investigators identified below, undertake:

- To observe the principles laid down in the most recent NHMRC Statement on Human Experimentation and The Declaration of Helsinki. (See Appendix 1 for a summary of these documents)
- Not to commence this research project until approval is obtained from the Austin Health Human Research Ethics Committee
- Not to commence this research project unless adequate funding and expertise are available to enable the study to be undertaken in accordance with the principles of good research practice and in an ethical manner
- To provide additional information as requested by the Human Research Ethics Committee
- To provide annual reports to the Human Research Ethics Committee in the required format
- To maintain the confidentiality of all data collected from study participants
- To notify the Human Research Ethics Committee in writing immediately if any changes to the protocol are proposed and await approval before proceeding with the proposed change
- To notify the Human Research Ethics Committee in writing promptly if any serious adverse events occur after the approval of the committee has been obtained
- To act promptly upon advice of a serious adverse event to ensure the safety and well being of study participants
- To agree to an audit as required by the Human Research Ethics Committee
- That data and any tissue samples collected will be used only for the study for which approval has been given
- That security procedures will be applied to maintain confidentiality (in general this will involve removal of personal identifying information from data collection forms and computer files. Codes linking individuals to data will be stored in a locked cabinet. Access to identifying data on computer should be under password control).
- That access to data will be only to appropriately authorised persons
- That no data capable of identifying a particular individual will be published without the specific written consent of the participant

As the Principal Investigator, I additionally declare that:

- I will take responsibility for the confidential maintenance of records for 15 years after completion (or 7 years in the case of non-drug trials).

Signature (Principal Investigator)

Name (in block letters)

Date

We, the undersigned investigators, confirm the undertakings detailed on the previous page:

Signature (Investigator)

Name (in block letters)

Date

Signature (Investigator)

Name (in block letters)

Date

Signature (Investigator)

Name (in block letters)

Date

Signature (Investigator)

Name (in block letters)

Date

Acknowledgment of Supervisor (if student project)

I am satisfied with the scientific integrity and validity of the proposal:

Signature (Supervisor)

Name (in block letters)

Date

Acknowledgment of notification to Head of Department at Austin Health

I am aware that this research is being undertaken in my Department and am satisfied that processes are in place to assure the scientific integrity of this proposal:

Signature (Head of Department)

Name (in block letters)

Date

Non Drug Study Review Committee -Cover Sheet

Please complete this cover sheet as it contains information that is essential for the scientific review of your study and which is often omitted from applications. This cover sheet will aid in the assessment of your study

STUDY TITLE

.....

PRINCIPAL INVESTIGATOR

.....

STATE A CLEAR HYPOTHESIS / PRIMARY OBJECTIVE / RESEARCH QUESTION

.....

.....

OBJECTIVE AND AIMS

.....

.....

PRIMARY OUTCOME MEASURE

.....

.....

CONSENT - How will consent be obtainedWrittenVerbalOther

If not written give reason.....

STATE WHAT IS ADDITIONAL TO STANDARD CARE :

.....

STUDY NUMBERS

Total :.....

At Austin Health :.....

STATISTICS**Methodology**

.....

Sample Size

.....

Power calculations

.....

Human Research Ethics Committee

QUESTIONS FOR INVESTIGATORS CONCERNING THEIR PROJECT AND ANY GENETIC COMPONENT

1. Does your project entail the collection of information or samples for genetic analysis?
2. Does the protocol describe arrangements made for information and counselling to be given to potential participants when being recruited?
3. Has consent for genetic analysis specified that this will be for work relevant to this study only? or to other studies of this condition? or to any study?

Has the participant been counselled before informed consent has been requested?

4. What information about the participant will be available with the samples?
 - Full identification and access to clinical information?
 - Limited information e.g. demographic, diagnostic, clinical but not sufficient identification to permit subsequent tracing or data retrieval?
 - None?

Has the participant been counselled before informed consent has been requested?

5. Will the samples with or without the above categories of information be made available to any third party?

Has the participant been counselled before informed consent has been requested?

6. Is commercial exploitation of data or concepts derived from the samples planned or will it be permitted? Will there be direct gain to your Department or you personally?

Has the participant been counselled before informed consent has been requested?

CHECKLIST 1:

Human Research Ethics Committee

**CHECKLIST (2) TO DETERMINE WHETHER PROPOSED STUDY
COMPLIES WITH ETHICAL REQUIREMENTS.**

<u>INFORMATION – CLINICALLY ACQUIRED:</u>	YES	NO
GENETIC?	<input type="checkbox"/>	<input type="checkbox"/>
CLINICALLY ACQUIRED Clinically justified procedure.	<input type="checkbox"/>	<input type="checkbox"/>
AVAILABLE TO PATIENT	<input type="checkbox"/>	<input type="checkbox"/>

<u>INFORMATION – RESEARCH ACQUIRED:</u>		
GENETIC?	<input type="checkbox"/>	<input type="checkbox"/>
RESEARCH ACQUIRED	<input type="checkbox"/>	<input type="checkbox"/>
FEEDBACK	<input type="checkbox"/>	<input type="checkbox"/>
NO FEEDBACK	<input type="checkbox"/>	<input type="checkbox"/>
IDENTIFIED	<input type="checkbox"/>	<input type="checkbox"/>
DE-IDENTIFIED.	<input type="checkbox"/>	<input type="checkbox"/>
ADEQUATE COUNSELLING ARRANGED Availability including timing and cost issues. Adequacy of resources e.g. qualification of Personnel follow-up.	<input type="checkbox"/>	<input type="checkbox"/>
NO ADEQUATE COUNSELLING ARRANGED. Availability including timing and cost issues. Adequacy of resources e.g. qualification of Personnel follow-up.	<input type="checkbox"/>	<input type="checkbox"/>

CHECKLIST 2

If your project contains any genetic testing please complete this form and add it to the application package.

Human Research Ethics Committee

LIST OF QUESTIONS FOR POTENTIAL PARTICIPANTS TO ASK INVESTIGATORS ABOUT RESEARCH INVOLVING GENETIC TESTING

You have been invited to participate in research involving genetic materials.

You may be interested in asking the researcher these questions after you have looked over the written information, and before you consent to be involved in the research project.

1. What do you think you might find out in this research?
2. Will I be able to get my results?
3. Who else will get a copy of my results?
4. If I choose to find out the results, what will this mean to me?
5. If I agree to participate what arrangements have been made for my independent counselling and who is the independent counsellor?
6. How might the results affect my family?
7. If I choose to get the results, how long will it be before I get them?
8. If I choose to get the results, who will help me to understand what they mean for me and my family?
9. What will happen to my **specimen or sample**? Will it be used in other studies?
10. Will my results have any effect upon my job, my being able to get insurance, **or my status in legal matters**?
11. What will happen if this research leads to the manufacture of commercial products?

For more information about ethical issues concerning this research you may contact

Dr Andrew Crowden

Chairperson Austin Health Human Research Ethics Committee,

Telephone 9496 2901

There is more general information about research ethics issues at
http://www.nhmrc.gov.au/your_health/issues/genetics/publications.htm

CHECKLIST 3

If your project contains any genetic testing, please complete this form and add it to the Participant Information and Consent Form as the final page



HUMAN RESEARCH ETHICS COMMITTEE

DEPARTMENT: PHARMACY

Declaration by Pharmacy Clinical Trials Manager

(This document is to be completed and signed off prior to submission.)

PRINCIPAL INVESTIGATOR (name):

TITLE OF PROJECT:.....

.....

PROTOCOL NO:.....

I have discussed this study with the Principal Investigator or his/her representative and have seen the application and protocol. The Pharmacy is

- Unable** to support the study within the present resources of the Pharmacy Department **but willing** to support it with financial assistance as specified in the box below.

- Charges according to document *Austin Health Pharmacy Services and Charges for Sponsored Clinical Trials **
- Charges according to document *Austin Health Pharmacy Services and charges for Non-Commercially Sponsored Studies e.g. Ludwig, ALLG*
- Charges according to document *Austin Health Pharmacy Services and Charges for Non-Sponsored Clinical Trials **

**each document available from pharmacy upon request*

FUND TO BE CREDITED: Pharmacy Clinical Trials Y2005

FUND TO BE DEBITED :

- Unable** to support the study on the following grounds

Investigator's Statement :

I have discussed this project withand appropriate arrangements have been made for this service/department to assist with this project as outlined above.

Signature:

Date:...../...../.....

Principal Investigator

Signature:

Date:...../...../.....

Pharmacy Clinical Trials Manager

HUMAN RESEARCH ETHICS COMMITTEE

DEPARTMENT: PATHOLOGY

Declaration by Pathology Clinical Trials Co-ordinator

(This document is to be completed and signed off prior to submission)

<p>PRINCIPAL INVESTIGATOR (name):</p> <p>TITLE OF PROJECT:.....</p> <p>.....</p> <p>PROTOCOL NO:.....</p>
--

I have discussed this study with the Principal Investigator and have seen the application and protocol. The Pathology Dept is

- Able** to undertake the investigations indicated with the present resources of the Pathology Department.

- Unable** to undertake the investigations within the present resources of the Pathology Department **but willing** to undertake them with the agreed level of financial assistance (detailed in *Pathology Department Clinical Trials/Research Declaration*).

FUND TO BE CREDITED: Y8050-36102

FUND TO BE DEBITED:

.....

- Unable** to undertake the investigations on the following grounds:

--

Investigator's Statement :

I have discussed this project withand appropriate arrangements have been made for this service/department to assist with this project as outlined above.

Signature:

Date:...../...../.....

Principal Investigator

Signature:

Date:/...../.....

Pathology Clinical Trials Co-ordinator

CLINICAL TRIALS APPLICATION

PATHOLOGY TRIAL NO.	
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1. PROJECT DETAILS

Title of project/study			
Protocol no:		Dept./Unit	
Principal Investigator		Research Coordinator	
Name:			
Address:			
Phone:			
Email:			
No. patients		No. episodes/visits	
Start date		End date	
HREC approval status			

2. PATHOLOGY SERVICES (For details of special conditions, see below)

<i>ITEM</i>	<i>CHARGE*</i>		
Pathology laboratory initial set up fee – includes protocol review, documentation, IT set up, administration & accounts			
Analyte/test/service	Episodes/visits per pt	Is the test additional to routine care? Y/N	PATHOLOGY USE ONLY Charge per episode*

***Note: Only services additional to routine care will be charged. Note that additional GST may be applicable. See Section 5. 'Account details'**

3. SPECIAL CONDITIONS

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4. SPONSOR DETAILS

Funding source (please tick)	Commercial		NHMRC		AHMRF		Other	
Details								

5. ACCOUNT DETAILS

Austin Health applicants only	Payment account type eg. SPF, cost centre, AHMRF, other	Account no:	GST applicable? (Pathology use only)
All applicants: Person responsible for account payment			

PATHOLOGY APPROVAL

Signature of Pathology Trial Coordinator _____

Name: _____ Date: _____

UNDERTAKING BY PRINCIPAL INVESTIGATOR OF TRIAL/STUDY

- Agrees to be responsible for funding arrangements between Austin Pathology and the sponsoring organisation
- Agrees to ensure that adequate funds are available to cover the agreed costs and that payment of invoices is within the time frames set out by Pathology
- Agrees to any conditions set out by Pathology
- Recognises that default of payment may preclude approval of future studies
- Will contact Pathology prior to commencement of the trial
- Agrees that if the trial has not commenced within 3 months of this declaration, will re-confirm costs with Pathology
- Agrees to notify Pathology upon completion of the study

Signature of Principal Investigator: _____

Name: _____ Date: _____

Pathology Use Only – Unit Manager Sign Off

Anat Path		Haem		Trials	
Biochem		Micro		App Rec	
CSR		Spec Collection			

Department of Radiology

Radiology Clinical Trials Protocol Form Austin Radiology		
Contact Details:		
Copy of study protocol submitted to Radiology? Please Tick Yes or No:		
	Yes	No
Trial Title:		
Protocol Number:		
Principle Investigator and Trial Coordinator:		
Site Coordinator:	MO:	Pager No:
Department/Institute:		
Contact Number:		
E-mail Address:		
Trial Details:		
Number of Patients:	Total expected no. of exams per patient =	
	Total expected number of exams =	
Date of Trial Commencement:	Trial Completion Date: (estimate)	
What imaging is required? (please tick)		
CT	MRI	US
Plain Xray	Other	
How frequent will the scans be?		
Is the imaging standard or non-standard?		
Please state if these scans are billable to the trial	Yes	No
Do images need to be de-identified?	Yes	No
Is specific reporting required (eg RECIST)?	Yes	No
Dos the study require a phantom and calibration?	Yes	No
Is there a radiography manual?	Yes	No

Is anyone required to attend a start up meeting?	Yes	No
Please specify here if scans are required to be performed at particular time or day of week:	Yes	No
Do you require anything else from the Radiology Department?	Yes	No
Sponsorship/Funding Details:		
Pharmaceutical Company:	Yes	No
NH&MRC:	Yes	No
AHMRP:	Yes	No
Other (please specify):		
Billing/Invoice Details:		
Option A		
Transfer of funds from your Cost Centre Number (For internal debtors)	Cost Centre	Account No
Option B		
Invoice sent via Finance Department (cannot be invoice from one internal dept to another)	Yes	No
Option C		
Please supply name and address to appear on invoice (Only applies to external debtors)		
Signature of Principal Investigator:		
Please return this form to Jenny Hollaway, Research Administrator, Radiology Department, Level 1, Austin Hospital, Heidelberg 3084 Phone 9496 2074 Email: jennifer.hollaway@austin.org.au		
Approved by Director of Radiology:		
Date:		
Comments:		

**DEPARTMENT OF NUCLEAR MEDICINE AND CENTRE FOR PET
RESEARCH CLINICAL TRIALS PROTOCOL FORM
NUCLEAR MEDICINE DEPARTMENT-**

DATE:		
Copy of study protocol submitted to Nuclear Medicine:	<u>Yes</u>	<u>No</u>
Trial Title:		
Protocol Number:		
Principal Investigator/Trial Coordinator:		
Department/Institute:		
Contact Number:		
E-mail Address:		
Pager Number:		
SPONSORSHIP/FUNDING (Please Tick)		
Pharmaceutical Company:	Yes	No
If Yes, What is their Name?		
NH&MRC:	Yes:	No
AHMRF:	Yes	No
Other: (Please Specify)		
BILLING DETAILS (Please Tick)		
Transfer of Funds?	Yes	No
Invoice to be Sent?	Yes	No
As Patient Presents?	Yes	No
Invoice Quarterly?	Yes	No
<u>TRIAL DETAILS</u>		
Number of Patients:		
Date of Trial Commencement:		
Trial Completion Date (estimate):		
Modalities: (Please Tick)	Nuc. Med	PET
	Therapy	Other
Cost per scan or	\$	
Cost per patient	\$	
Report to be forwarded to:		
Study to be performed at (please tick)	Austin	Repat
Day of the week patient to be scanned, if known?		
Signature of Principal Investigator:		
Please return this form to Ms. Morena Scalzo, Administrative Assistant, Department of Nuclear Medicine and Centre for PET Austin Health, 145 Studley Road, Heidelberg 3084 Ph: 9496 5163		
Approved by Director of Nuclear Medicine		
Date:		



Centre for Positron Emission Tomography

Austin Health

Austin Hospital, Level 1, Harold Stokes Building,

Telephone: (613) 9496 3329 or 9496 5669 Facsimile: (613) 9458 5023

RESEARCH CLINICAL TRIALS PROTOCOL FORM

Study Protocol submitted to Centre for PET and approved for PET scans

DATE:		
Copy of Study Protocol submitted to Centre for PET? (If no, please submit a copy along with this form.)	<u>Yes</u>	<u>No</u>
Study/Trial Title:		
Protocol Number:	Ethics Number/Project Number:	
Principal Investigator/ Study/Trial Coordinator:		
Department/Institute:		
Contact Numbers:		
E-mail Address:		
Pager Number:		
SPONSORSHIP/FUNDING (Please Tick)		
Pharmaceutical Company:	Yes	No
If Yes, What is their Name?		
NH&MRC:	Yes	No
AHMRF:	Yes	No
Other: (Please Specify)		
<u>STUDY/TRIAL DETAILS</u>		
Number of Patients:		
Number of Scans Per Patient:		
Date of Study/Trial Commencement:		
Study/Trial Completion Date (estimate):		
Invoice request to be forwarded to: <u>Name</u>		
<u>Address</u>		
Cost PER SCAN for FDG scans:	\$	Notes/misc:
Cost PER SCAN for non-FDG scans:	\$ (if applicable)	
Tracer/Details:		
Report to be forwarded to:		
Day of the week patient to be scanned, if known?		
Signature of Principal Investigator:		
Please return this form to Ms. Anna Peretta or Morena Scalzo, Administrative Assistant, Department of Nuclear Medicine and Centre for PET Austin Health, 145 Studley Road, Heidelberg 3084. Ph: 9496 5163		
APPROVALS (Centre for Positron Emission Tomography)		
_____ Date: ____ / ____ / ____		
Prof Andrew M Scott, Director, Centre for PET		
_____ Date: ____ / ____ / ____		
Mr Nick Alexopoulos, Manager, Department of Nuclear Medicine & Centre for PET		
_____ Date: ____ / ____ / ____		
Prof Chris Rowe, Director, Department of Nuclear Medicine & Centre for PET		
Date this form returned to Principal Investigator:		

**HUMAN RESEARCH ETHICS COMMITTEE
HEALTH INFORMATION SERVICES (HIS)**

DECLARATION - RESEARCH MEDICAL RECORDS

This document is to be completed and signed off for all studies **prior to submission.**

Principal Investigator To Complete This Section:

PRINCIPAL INVESTIGATOR (name): Contact Person Phone: PROTOCOL NUMBER TITLE OF PROJECT:
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Please Tick	Level of Ethics Fee Payable.	Medical Record Fee
<input type="checkbox"/>	<p align="center">Sponsored – Commercially</p> <p>Medical records will be required at any time during the life of the study.</p> <p><u>Details For Tax Invoice:</u></p> <p>Sponsor.....</p> <p>Contact Name For Invoice.....Phone</p> <p>Address.....</p> <p>Suburb..... State..... Post Code.....</p> <p align="center">OR</p> <p><u>Transfer Of Funds:</u> Fund To Be Credited: Health Information services P0205 - 57801 Fund To Be Debited:</p>	<p>\$750 plus GST</p> <p align="center"><i>One-off up front fee</i></p>
<input type="checkbox"/>	<p>Sponsored: Commercially</p> <p>Medical records will never be required during the life of the study. If this changes in the future, the Principal Investigator must advise the Operations Manager, HIS and provide billing details.</p>	<p>No fee</p>
<input type="checkbox"/>	<p>Sponsored – Non Commercial</p>	<p>No fee</p>
<input type="checkbox"/>	<p>Non sponsored external study</p>	<p>No fee</p>
<input type="checkbox"/>	<p>In-house study</p>	<p>No fee</p>

Signature Of Principal Investigator Date:
--

Health Information Services To Complete This Section:
<p>I have discussed this study with the Principal Investigator or his/her representative and have seen the application and protocol. I am able/unable to support this study.</p>
Signature: Date:..... Operations Manager, HIS

Therapeutic Devices

Additional Information required if not present in Protocol:

Describe the nature of the device, including details of the design, composition, specification, mode of action and application of the device: Include whether of human or animal origin:

Is the device registered on the Australian Register of Therapeutic Goods (ARTG) Yes / No

Is the device being considered under the Clinical Trial Exemption (CTX) Scheme Yes / No

Is the device being considered under the Clinical Trial Notification (CTN) Scheme Yes / No

Please provide documentary evidence for the above

Signature from Andrew Moorhouse (p3007) indicating approval from Medical Engineering and Physics, to be obtained before submission to HREC:

Signature..... Date: / / .

Describe previous experiences relevant to the safety and efficacy of the device

Long-term follow-up – describe the intended procedures to ensure long-term follow-up of trial participants

Please provide (tick if present)

- relevant correspondence with other regulatory authorities (includes statements of the commercial or investigational status of device overseas)
- Relevant correspondence with other ethics committees
- All information concerning previous product recalls
- For devices of human or animal origin, provide evidence of compliance with Quarantine, where appropriate

PRINCIPAL INVESTIGATOR (name):

TITLE OF PROJECT:.....

.....

PROTOCOL NO:.....

All Austin Health services utilised in the study must be accounted for in the table below

Authorised signatures are necessary to confirm agreement that use of resources stated here will be reimbursed from study budget to department cost centres, organised by Investigator

Department	Cost \$	Amount to be reimbursed	Payment authorised by/on behalf of Principal Investigator	From Cost Centre	Agreement on behalf of department providing service	To Cost Centre
Pharmacy						
Pathology						
Nursing						
Medical						
Health Information Services						
Allied Health (Please detail)						
Cardiology						
Radiology						
MRI						
Nuclear Medicine						
PET						
Other services (please detail)						

NEW FEE STRUCTURE FOR 2010

Trials or studies submitted to the Austin Health HREC attract submission fees

Trials or studies submitted through the SERP process to Austin Health HREC attract submission fees.

Trials or studies to be run at Austin Health where Austin Health is a 'participating site' and the HREC review has been performed at another SERP reviewing HREC attract Research Governance fees (for both new protocols and protocol amendments).



ETHICS OR GOVERNANCE FEE

Principal Investigator:

Study Title or Protocol No.....

Please tick the appropriate box to indicate level of ethics fee payable

- | | | |
|--------------------------|---|------------------------------|
| <input type="checkbox"/> | COMMERCIALY SPONSORED | \$6050.00¹ |
| <input type="checkbox"/> | COMMERCIALY SPONSORED sub-studies | \$3025.00¹ |
| <input type="checkbox"/> | COMMERCIALY SUPPORTED (Investigator driven) | \$3025.00¹ |
| <input type="checkbox"/> | NON COMMERCIALY SPONSORED INVESTIGATOR COLLABORATIVE GROUP STUDIES | \$660.00¹ |
| <input type="checkbox"/> | NON SPONSORED (more than 1 site) | \$660.00¹ |
| <input type="checkbox"/> | IN-HOUSE STUDIES | \$200.00² |
| <input type="checkbox"/> | COMMERCIALY SPONSORED Protocol Amendment | \$660.00¹ |

1 Fee includes GST

2 In-house studies do not attract GST but must be paid by 'Transfer of Funds'

DETAILS FOR TAX INVOICE

Sponsor:.....

Contact Name for Invoice:.....

Address:.....

.....

Suburb:.....State:.....Post Code:.....

Or

DETAILS FOR TRANSFER OF FUNDS

SPF number:.....

Name of Department or SPF:.....

Charge \$.....

Authorised by :

SignatureTitle

Name.....Date/...../.....

(Must be signed by a person authorized by the Finance Department to transfer funds)

**ETHICS PAYMENT – *Fast-Track*
(*Out-of-session*)**

Principal Investigator:

Study Title or HREC Project number

The Fast – Track process is only available in certain circumstances. It is not a process that can be requested without substantiation of need.

It is not available for new protocols/projects.

Examples of acceptable Fast – Track requests include:

1. Updated Participant Information and Consent Forms:

Trial still recruiting *and/or*

- New information may impinge on Participants willingness to continue in trial
- New information results in altered trial procedures/requirements/conditions and Participants must re-consent to altered conditions

2. Advertisements to aid recruitment

3. Media releases

4. Protocol amendments based on safety changes

Commercially sponsored \$300* (+ GST)

** this payment is additional to any other required payment*

DETAILS FOR TAX INVOICE

Sponsor:.....

Contact Name for Invoice:.....

Address:.....

.....

Suburb:.....State:.....Post Code:.....

Cover Page

Delivered to: Research Ethics Unit	
Date Delivered to Research Ethics Unit:	
Project Name:	
Protocol No.	
Phase:	Investigator Initiated <input type="checkbox"/>
Standard Medicines Australia Agreement <input type="checkbox"/>	Collaborative Study <input type="checkbox"/>
Total Sponsorship (not per patient) \$	CTX Study <input type="checkbox"/>
GST included	Yes <input type="checkbox"/> No <input type="checkbox"/>
Payment Details: Account Funds to be paid into	
Proposed start date:	
Proposed completion date:	
Indemnity Provided:	Yes <input type="checkbox"/> No <input type="checkbox"/>
Certificate of Insurance attached:	Yes <input type="checkbox"/> No <input type="checkbox"/>
Trial Co-ordinator	
	Address:
	E-mail
	Tel:

Guidelines for Preparation of the Participant Information and Consent Form

The Human Research Ethics Committee will pay particular attention to the PI&CF

- The Participant Information and Consent Form is to be an **integrated document** with sequential **page numbering**, it must have a **version number** and **date** on each page
- If the project contains any **genetic testing** the Austin Health Genetics Check List 3 must be attached as the final page of the integrated document
- It is a **different** and **separate** document from the Lay Summary (*Question 1.3*) and it is not sufficient to just copy or 'paste' from one document to the other
- It should provide an accurate description of the nature of the study and any potential risks, discomforts or inconveniences that may be encountered by the participant
- It must be **consistent** with information provided in the Protocol
- It should be expressed in **plain language**, in the **second person**
- The preferred font is **Arial 12 point**
- It is preferably that participants initial each page of this document during the consent process to indicate they have read and understood the requirements of the study.

ATTACHED ALSO FOR YOUR ASSISTANCE

PICF template for Clinical Drug Trial or Device Trial

http://www.health.vic.gov.au/ethics/downloads/picf_drug.doc

PICF template for Clinical Non-drug/device trial

http://www.health.vic.gov.au/ethics/downloads/picf_nondrug.doc

PICF template for Health and Science Research -

http://www.health.vic.gov.au/ethics/downloads/picf_health.doc

The Participant Information and Consent Form should include:

- Full project title
- Principal Investigator's name, and title or position
- At the beginning, an invitation to take part in the study (eg: "You are invited to participate in a research project involving..... because.....")
- That it is a research project and that participation is entirely voluntary and can be terminated at any time, for any reason, without prejudice and without giving any reason
- The treatment/s and the use of a placebo with a clear statement that some participants may receive an inactive substance. This should be included on page 1. Do not refer to a placebo as a 'dummy drug'.
- A clear indication if it is a student project and the full name of the degree the student is aiming for
- Encouragement to ask questions

- The nature or purpose of the study including, where appropriate:
 - The possibility of random assignment to different treatment groups, and this means by which this is done eg: 'like the tossing of a coin
 - All procedures, drugs or radiation including all invasive procedures, venipuncture or exercise tests, together with an assessment of any potential risks, foreseeable side effects and discomforts
 - A clear statement as to what in the study is additional to standard treatment / care
 - If any usual treatment is being withheld and the implications of this
 - A clear statement whether or not males should avoid fatherhood while on a study drug and for any period after the end of the trial
 - It is essential that for all blood/tissue samples it is noted whether they are for routine tests (and will be destroyed after testing) or for trial tests. If they are for trial tests, the following must be noted:
 - The limits of testing allowed on the samples, the use to which they can be put and who will oversee the adherence to these conditions.
 - Whether the samples will be identified, coded or de-identified
 - Where (city and country) for how long and by whom (name) storage of samples will occur
 - Final fate of the samples
 - What is required of the participant, ie; lifestyle changes, diet, visits to the hospital and the likely time involved, the duration of the study and any out-of-pocket expenses
 - A clear indication if audio or videotaping is required, or any questionnaires to be answered
 - The precautions that will be taken to ensure the confidentiality of the participant
 - A description how any risk of physical and/or psychological stress, therapeutic failure or adverse events in either the short or the long term from participation will be dealt with
 - Whether or not travel and parking expenses will be reimbursed and how this will occur e.g. taxi vouchers will be supplied or expenses will be reimbursed on production of a receipt (and state the maximum amount available per visit).
 - The amount of any payment, when it will be paid and what amount the pro rata payment will be if they withdraw before completion.
 - A description of circumstances under which participation may be terminated - including consideration that will be given to new findings arising during the study period
- A statement that the records dealing with the participant will be kept under safe storage for 15 years after completion (25 years in the case of trials involving children and 7 years in the case of non drug trials) and will then be destroyed, or if retained that no further testing will be performed without a further consent being obtained
- A statement that participant records may be inspected for purposes of data audit by authorised persons and whose authorised persons may be
- That in drug trials, compensation will be available should serious injury occur that is directly related to the study medication
- The name of, and means by which, an appropriate person may be contacted by a participant during the course of the study or in the case of an emergency
- Serious risks arising from involvement in research, such as driving a vehicle after treatment or pregnancy risks or risks to embryo, foetus or breast-feeding infants **should be highlighted in bold**
- The name, and means by which, the Ethics Committee may be contacted by a participant the required wording, **in bold** is:

If you wish to contact someone, independent of the study, about ethical issues or your rights or to make a complaint, you may contact Dr Andrew Crowden,

You may need to use a number of PICFs depending on your target audience.

- Participant
- Parent / Guardian – for use when participants are under the age of 18
- Person Responsible – for use when participants are not competent
- Older Child Under 18
- Carer – participating in a trial in their own right.

Investigators are encouraged also to have a Participant Information and Assent Form for older children to sign, written at a level appropriate for the age of the children being recruited.

Investigators should have a Participant Information Sheet and Consent for Continuation in Research Form in instances where participants are likely to regain capacity and original consent was obtained from the Person Responsible.

Austin Health does not required a Revocation of Consent form since participants are not required to withdraw in writing.