

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>
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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:

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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	
Biochem		Micro	
CSR		Spec Collection	