

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**)*

PRINCIPAL INVESTIGATOR (name): Click or tap here to enter text.

TITLE OF PROJECT: Click or tap here to enter text.

PROTOCOL NO: Click or tap here to enter text.

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: Click or tap here to enter text.

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

Click or tap here to enter text.

Investigator's Statement :

I have discussed this project with Click or tap here to enter text. and appropriate arrangements have been made for this service/department to assist with this project as outlined above.

Signature:

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

Signature of Pathology Trial Co-Ordinator:

Name:

Date:

Quote #

CLINICAL TRIALS/RESEARCH APPLICATION

(For Clinical Trial Office Use Only)

PATHOLOGY TRIAL NO.	
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1. PROJECT DETAILS

Quote #

Title of project/study	Click or tap here to enter text.		
Protocol no:	Click or tap here to enter text.	Dept./Unit:	Click or tap here to enter text.
Principal Investigator		Research Coordinator	
Name:	Click or tap here to enter text.	Click or tap here to enter text.	
Address:	Click or tap here to enter text.	Click or tap here to enter text.	
Phone:	Click or tap here to enter text.	Click or tap here to enter text.	
Email:	Click or tap here to enter text.	Click or tap here to enter text.	
No. patients:	Click or tap here to enter text.	No. episodes/visits:	Click or tap here to enter text.
Start date:	Click or tap to enter a date.	End date:	Click or tap to enter a date.

Please supply a copy of the trial protocol and any supporting documentation.

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

ITEM	CHARGE* (Pathology Use Only)			
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*	Panel Codes
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Quote #

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Note that **additional GST may be applicable**. See Section 5. 'Account details'

3. SPECIAL CONDITIONS

Click or tap here to enter text.

4. SPONSOR DETAILS

Funding source (please tick)	Commercial	<input type="checkbox"/>	NHMRC	<input type="checkbox"/>	AHMRF	<input type="checkbox"/>	Other	<input type="checkbox"/>
Details	Click or tap here to enter text.							

5. ACCOUNT DETAILS

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

6. PATHOLOGY APPROVAL

Signature of Pathology Trial Co-Ordinator: _____

Name: _____ Date: _____

UNDERTAKING BY PRINCIPAL INVESTIGATOR OF TRIAL/STUDY

- Agrees to be responsible for funding arrangements between Austin Pathology and the sponsoring organisation

Quote #

- 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
- Recognises that over the length of the study/trial there may be changes in methodology and instrumentation
- Recognises that this quotation is only valid if the study commences within 6 months.
- Recognises that costs may change in line with changes in MBS fees, consumable or testing price increases and therefore original pricing may vary.
- Agrees to notify Pathology upon either completion or withdrawal of the study.

Signature of Principal Investigator: _____

Name: _____ Date: _____

Pathology Use Only

Application Received in Trials	
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