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 to Ethics****)*

**PRINCIPAL INVESTIGATOR** (name):

**TITLE OF PROJECT**:

**PROTOCOL NO**:

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 with ……………………………….. and appropriate arrangements have been made for this service/department to assist with this project as outlined above.

Signature: …………………………………………… Date:……./……./…….

Signature: ……………………………………………. Date: ……./……./…….

  **Pathology Clinical Trials Co-ordinator**

**DEPARTMENT: PATHOLOGY**

###### CLINICAL TRIALS/RESEARCH APPLICATION

|  |  |
| --- | --- |
| PATHOLOGY TRIAL NO. |  |

**1. PROJECT DETAILS Quote #**

|  |  |
| --- | --- |
| 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 |  |

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

|  |  |
| --- | --- |
| ITEM | **CHARGE\*** |
| 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/collection additional to routine care? Y/N | PATHOLOGY USE ONLYCharge per episode**\*** |
|  |  |  |   |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

 Note that additional GST may be applicable. See Section 5. ‘Account details’

3. SPECIAL CONDITIONS

|  |
| --- |
|  |

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
* 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 and costs may change in line with changes in MBS fees.
* Agrees to notify Pathology upon either completion or withdrawal of the study.

|  |  |
| --- | --- |
| Signature of Principal Investigator: |  |
| Name: |  | Date: |  |

 Pathology Use Only – Unit Manager Sign Off

|  |  |
| --- | --- |
| Application Received in Trials |  |