ALFRED PATHOLOGY SERVICES
TRIAL / RESEARCH INSTRUCTION SHEET

1. Request for a trial, research or study costing should be made with the Trials Co-ordinator at Alfred Pathology Services (APS). Please allow at least 48 hours for the costing after the request is made.

2. The Trials Co-ordinator can be contacted for any queries, supply of request slips, accreditation certificates, Head of Laboratory CV, reference ranges, billing queries etc.

3. To enable costing of the trial the Pathology Declaration and Trial / Research Specimen Checklist, is to be completed and provided to APS with relevant pages of the study protocol and or the study instruction manual. Relevant pages can be photocopied.

   NB: Please request specific analytes on the Declaration and request slips to assist laboratory staff. Avoid requesting cluster tests, ie U&E's, and LFT's, as clusters may change throughout the life of your trial.

   Please also note that from time to time methodologies change. It is worth checking with the laboratory should you notice unaccounted change in your test population.

4. Special conditions should be specified on the Pathology Declaration, or attached to the Declaration and clearly highlighted. Special conditions include any requirement that is non-routine and or specific to the study protocol. This may include:

   - *collection tubes other than those supplied by APS*
   - *special bleeding requirements*
   - *out of hours requirements*
   - *if specimens will be batched*
   - *non routine processing of specimens*
   - *specific procedures*
   - *specific reagents*
   - *storage requirements*
   - *shipment of specimens*

   All special instructions and procedures should also be written clearly on the request slip for laboratory staff.

5. Once the study is approved you will be provided with:

   a) Estimated costing (required in Ethics submission)*
   b) Signed declaration (required in Ethics submission)
   c) Pathology ID labels that identify your unique Pathology client number

   ** The costing is a reflection of the study at the time of presentation to APS and does not take into account additional testing, more frequent testing, increased patient volume, MBS (Medicare Benefits Schedule) or secondary providers price variations.*

6. Pathology issued trial slips are to be used for all trial requests which are additional to routine patient care. These request slips help identify and track the specimens for correct handling, billing and reporting purposes. All trial requests are invoiced to the trial.

7. To avoid being billed for tests which are part of routine care, separate blood needs to be taken with an accompanying request slip completed with the patients' regular financial class. It is important that these requests do not include a trial number or they will be invoiced with trial specimens.

8. Any amendments to Pathology requirements in protocols after the trial has been approved, need to be communicated to APS. A revised costing will be performed to reflect any changes.

9. If APS does not provide a specific test required in a study protocol the requesting trial coordinator may need to negotiate an arrangement with a secondary provider. Where a test is non routinely sent out, all communication concerning test procedures and in some cases fees and invoicing need to occur directly between the trial coordinator and secondary provider. All specimen handling requirements for these tests must be discussed with APS.

10. Transport to a secondary provider may be available through APS if part of APS normal courier run. Specific inquiries need to be made.

11. Where it is required that tests offered by APS are to be sent to an outside laboratory it is the requesting units responsibility to arrange, pack and pay for the transport of specimens. Please note that couriers will charge the requesting unit for waiting time if your specimens are not ready at the time arranged by the Trial Co-ordinator.

12. The researcher or trial coordinator must inform APS when a trial is due to commence and when it has been completed.

13. Once the study has commenced, invoices will be forwarded on a monthly basis to individual researchers or coordinators and are payable by EFT/cheque or ICAN within 30 days. Items are invoiced according to the work actually requested and performed for a trial even if not part of the original agreement.

14. Trials may be subject to MBS price variations. Negotiated fees may be subject to review at any stage of a trial.

15. EFT/cheques and all ICANS are to be forwarded to the Trial Co-ordinator at APS. Internal Special Purpose fund transfers arranged with Finance must also be communicated with the Trials Co-ordinator at APS.

16. Trials containing tests requested in significantly high volume must be identified in advance with the Trials Co-ordinator to ensure appropriate laboratory management.

17. Trial tests will be completed as soon as practicable. Any requirement for tests to be completed other than within the confines of our standard turn-around-time must be identified in advance with the Trials Co-ordinator and are subject to approval prior to the commencement of any testing.

18. This declaration must be signed prior to the commencement of any trials requests. All trials requests will not be accepted until this paperwork has been provided.

19. A copy of the approval granted from the Ethics committee must be provided to the Trials Co-ordinator. All trials requests will not be accepted until this paperwork has been provided.

If there are any queries in regard to any of these points please contact Alfred Pathology Service on 9076 2725

ALFRED PATHOLOGY SERVICES
DECLARATION FROM RESOURCE CENTRE MANAGER

Project Details:

Title of project/ study:

Department/Unit requesting:

Researcher: **Extension:**

Co-ordinator: **Extension:**

Expected commencement date: **Expected completion date:**

Submission date for The Alfred Ethics Committee approval?

Resources required:

Analyte	**Occasions**	**Number of Patients**	**Is the test additional to Routine to Patient care?* Y/N**

**** Please note only tests Additional to Routine Care will be costed.***

Account Details:

Source of Trial Funding:

Person responsible for account payment:

Please attach any special conditions relating to this trial.

Pathology Services:

Trial number allocated by Pathology Services: ……..….

Signature:.....….....……..

Name:.....……..….....Date:.……..…

Undertaking by Chief Investigator of the trial:

- Agrees to be responsible for all funding arrangements between The Alfred and the sponsoring body;
- Agrees to ensure that adequate funds are available and that payment of invoices is from an Alfred hospital cost centre or special purpose fund and will cover all the agreed costs within the time frames set out by the supporting department;
- Agrees to any conditions outlined by the supporting department;
- Recognises that default of payment may preclude approval of future trials involving him/her;
- Will contact the supporting service at the commencement of the trial;
- Agrees if the trial has not commenced within 6 months of the costing date, will re-confirm prices with the supporting department;
- Agrees to notify the relevant support services upon completion of the trial.

Signature of Chief Investigator:.....…….....……..

Name:.....….....Date:.....…….....

THE FOLLOWING QUESTIONS ARE INTENDED TO IDENTIFY NON-STANDARD HANDLING REQUIREMENTS

	Y	***N***
ANALYTICAL ISSUES		
1. Are all the tests listed in this year's edition of Alfred Pathology Handbook? *Please contact (03) 92763888 to obtain a copy of the APS Handbook.*	☐	☐
2. Are any of the specimens in this trial from **non-human** sources?	☐	☐
3. Will the specimens undergo any preparation or handling before reaching Pathology? *eg: storage, centrifugation or re-labelling.*	☐	☐
4. Is a *specific methodology* required for any tests?	☐	☐
5. Is there a requirement to *maintain* the same methodology throughout the course of the trial? *(If 'Y', it is generally not possible to guarantee this for trials exceeding 6 months.)*	☐	☐
6. Do you anticipate any of the results obtained might lie outside the range usually seen in routine pathology specimens? *ie. be extremely abnormal.*	☐	☐
SPECIAL HANDLING REQUIREMENTS		
7. Will patients be identified with an Alfred UR number? *If not an Alfred UR number, will patients be uniquely identified in some other traceable and secure way? Please specify*……. ……	☐	☐
8. Will specimens arrive with a standard Alfred Pathology request form or Alfred Pathology batch sheet (*consult*) on each occasion?	☐	☐
9. Will all specimens arrive in standard Alfred Pathology collection tubes?	☐	☐
10. Apart from reporting the trial number, is any special data entry or handling required beyond that normally associated with the tests requested?	☐	☐
11. Will specimen be received outside normal office hours?	☐	☐
12. *Will any results be required urgently?* **	☐	☐
13. Will the specimens arrive in batches >10 at a time?	☐	☐
14. Is there any requirement for long term retention or storage of specimens?	☐	☐
15. Are there any "chain of custody" concerns with these specimens?	☐	☐
CLEARLY DESIGNATED RESPONSIBILITY		
16. Will specimens always be clearly identified as part of this trial?	☐	☐
17. If HIV testing is to be performed, will adequate counselling be given? *If there are any queries in regard to HIV counselling, please contact Dr Denis Spelman (Internal beep 4226.)*	☐	☐
18. Who is to be notified of any expected or unexpected *critical results*?		

Name:…….……..……..…….Phone:……..……Beeper:……..…**After Hours*:…...……

Please also provide relevant pages of the study protocol or instruction manual.