

## ALFRED PATHOLOGY SERVICES TRIAL / RESEARCH INSTRUCTION SHEET

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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 client number labels, 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.*

1. 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, CMBS (Commonwealth Medical Benefits Schedule) or secondary providers price variations.*

1. Pathology ID labels are to be applied to all trial requests which are additional to routine patient care. Please ensure the financial class of these requests are labelled as RES. The labels help identify and track the specimens for correct handling, billing and reporting purposes. All requests with labels are invoiced to the trial.
2. 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 patient's regular financial class. It is important that these requests do not include a trial number or they will be invoiced with trial specimens.

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3. Any amendments to Pathology requirements in protocols after the trial has been approved, need to be communicated to Alfred Pathology Services. A revised costing will be performed to reflect any changes.
4. 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.
5. Transport to a secondary provider may be available through APS if part of APS normal courier run. Specific inquiries need to be made.
6. Where it is required that tests offered by APS are to be sent to an outside laboratory it is the requesting unit's 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.
7. The researcher or trial coordinator must inform Alfred Pathology Service when a trial has been completed.
8. Once the study has commenced, invoices will be forwarded on a quarterly basis to individual researchers or coordinators and are payable by 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.
9. Trials may be subject to CMBS price variations. Negotiated fees may be subject to review at any stage of a trial.
10. Cheques and ICANS are to be forwarded to the Trial Co-ordinator at Alfred Pathology Service. Internal Special Purpose fund transfers arranged with Finance must also be communicated with the Trials Co-ordinator at APS.

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