Approval Process, Terms and Conditions

1. Principal Investigators (PI) for all clinical trials, QA/low risk and other research projects using Melbourne Health Pathology service are required to complete a *Pathology Approval for Research* application form using one of the following forms:

   - Clinical trial/research projects – Melbourne Health and external researchers (Approval form)
   - QA/Negligible risk projects (Approval form)

   Submit the completed form and study protocol to the Pathology Clinical Trials Coordinator at maria.bisignano@mh.org.au

2. For projects submitted to the MH HREC, a signed *Statement of Approval* form (Pathology) for Research Governance will be provided. If you are external to Melbourne Health (MH) a Laboratory Services Agreement will also be provided for signature. Please allow at least two weeks for approval to be finalised

3. Clinical trials / research projects requiring pathology tests that are considered to be part of routine clinical care for study participants must also be submitted for review and approval

4. Approval, establishment and per test or service fees apply. The costs and conditions of approval to use the Pathology services of are based on the information provided at the time of request and subject to change. Fees are reviewed annually

5. Any protocol amendments affecting Pathology services will require review and approval by the Pathology Clinical Trials Coordinator. Fees apply for amendments

6. For clinical trials / research projects conducted at Western and Sunshine hospitals, if you require access to tumour tissue collected prior to 1st October 2011, this is held by MHSPS and you will require approval from the Pathology Clinical Trials Coordinator. Submit you application as above

7. Protocol specific Pathology request forms will be provided for your clinical trial / research project. These request forms help identify and track specimens for correct handling, reporting and billing. Where special handling of specimens is required, laboratory protocols must be in place before a clinical trial / research project can commence

8. To avoid being billed for tests that are part of routine clinical care:
   - separate specimens are to be drawn for trial and routine care tests and sent to Pathology with separate trial and non-trial request forms
   - the request form for routine clinical care testing will have the patient's regular financial class. It is important that these requests do not include the HREC number or they will be charged to the trial
   - do not handwrite additional tests on the trial specific request forms. Any handwritten tests will be charged to the trial

9. Billing occurs at the end of each month. The debtor is responsible for ensuring adequate funds are available to pay for services

10. The Pathology Clinical Trials Coordinator should be contacted upon completion of the trial