Western Health

Dorevitch PATHOLOGY

Research Pathology Approval Process

All clinical research trials involving pathology testing require Site Specific Approval following this process.

Projects involving **data extraction only**:

- Determine whether your data can be obtained from WH Performance Unit.
- If data required from pathology provider, forward data requirements WHS-Research Pathology along with completed Statement of Approval Form
- Once data extraction agreed with pathology provider, SOA to be signed by Operations Manager, Medical Imaging and Pathology Contract

Trials requiring **Standard Clinical Care** pathology tests:

- Complete approval form
- Complete Schedule of Investigations form; or provide schedule from the study protocol *(do not send the entire study protocol)*

Trials requiring **Above Standard Clinical Care** pathology tests:

- Complete approval form
- Complete Request for Quote form, which includes the Schedule of Investigations *(do not send the entire study protocol)*

The information regarding tests required must be sufficiently detailed to enable Dorevitch to understand exactly what is required.

If you have any questions regarding the approval process, please contact Kellie Foran, Quality Facilitator Pathology and Medical Imaging on 8345 0529 or via email Kellie.Foran@wh.org.au

Email completed forms to **WHS-Research Pathology**

- Emails sent to this group address go to all relevant staff at both Dorevitch and Western Health
- Use the summary title as the email subject title to ensure ease of tracking correspondence related to each study.
- You will receive email confirmation of receipt of your documentation
- Please respond to emails promptly – A delay in response of more than 14 days may result in an amendment to the date of submission.

The researcher or delegate will be notified if the information provided is not detailed enough for Dorevitch to complete a quote for services. Please provide required additional information to allow the application to proceed.

Allow up to 14 business days for the completion of quotes from the date of submission.

Completed quotes will be emailed to the researcher or delegate by Dorevitch. Coordinator or Investigator must notify via **WHS - Research Pathology** email that the quote has been accepted.

Queries regarding a quote should be directed to the Operations Manager, Pathology and Medical Imaging by email **WHS - Research Pathology** or by phone: **8345 0509**

Once the quote has been accepted the Pathology Approval form will be signed by the Operations Manager and returned by email

Trial Specific Pathology Request Forms
Once approval has been finalised, Dorevitch will produce trial specific pathology forms for above Standard Clinical Care tests.
Dorevitch will forward request forms 14 business days following approval
These forms must be used to ensure costs are allocated according to quote

Cost implications for Western Health are taken into account during the approval process