

Office for Research 3rd Floor, Western Centre for Health Research and Education Sunshine Hospital Furlong Rd. St Albans VIC 3021 Tel. +61 3 8395 8074 Fax. +61 3 8395 8259 ABN 61 166 735 672

Memorandum

Subject:	SITE AND NAME CHANGES AT WESTERN HEALTH AND THE IMPACT ON RESEARCH ACTIVITIES AND RESEARCH GOVERNANCE REQUIREMENTS
Date:	23 September 2014
From:	Dr Tam Nguyen, Manager, Office for Research
To:	All Research Stakeholders

There are a number of changes occurring at Western Health such as the relocation of wards from Western (Footscray) Hospital to Sunshine Hospital as well as a name change of Western Hospital to Footscray Hospital. This will affect a number of research projects undertaken at Western Health. The Office for Research understand and are aware of the number of concerns and have received many queries as to what this would mean for research at Western Health.

RELOCATION

In regards to the relocation of wards, this will require a number of governance amendments:

- Any projects that would require participants to attend the Sunshine Hospital site instead of the Western (Footscray) Hospital site will need to advise participants of the location changes and any Participant Information and Consent Forms (PICFs) will need to be revised to the appropriate site name and participants may need to be re-consented.
- New Statement of Approvals (SOA)/Head of Supporting Department authorisations will also need to be provided if services are now required from Sunshine Hospital instead of Western (Footscray) Hospital.
- Clinical Trial Notification (CTN) Forms The Therapeutic Goods Administration (TGA) would require a revised CTN of any site location changes.
- Any other amendments associated with the relocation e.g. personnel changes.
- A grace period will be given until <u>01 June 2015</u> for relocation details changes.

NAME CHANGE

The name of Western Hospital will officially become **Footscray Hospital** from <u>01 October 2014</u>. This will require a number of governance amendments such as:

• Participant Information and Consent Forms (PICFs) will need to be revised to the appropriate site name and participants may need to be re-consented.



Memorandum

Office for Research 3rd Floor, Western Centre for Health Research and Education Sunshine Hospital Furlong Rd. St Albans VIC 3021 Tel. +61 3 8395 8074 Fax. +61 3 8395 8259 ABN 61 166 735 672

- Clinical Trial Notification (CTN) Forms The Therapeutic Goods Administration (TGA) would require revised CTN of any site name/location changes.
- Clinical Trial Research Agreements (CTRA) will not need to be revised as the Institution should have been named as "Western Health" and the agreement is not site specific and would not require an amendment.
- Medicines Australia Form of Indemnity for Clinical Trials will not need to be revised as the Institution should have been named as "Western Health" and the Indemnity is not site specific and would not require an amendment.
- A grace period will be given until <u>01 January 2015</u> for name change requirements.

The submission process remains the same as the current amendment requirements; please see the Western Health Research & Development Internet and Intranet websites for submission requirements. Please note that no amendment fees will be charged for these changes.

Please note that the Office for Research will be inundated with the above amendments; acknowledgements and processing of documents will be delayed and the usual 2 week response timeline will not be applicable for submissions relating to the above.

Thank you for your patience and understanding through the new changes occurring at Western Health.

HAVE ANY QUESTIONS?

We appreciate that these changes may generate further questions. Please feel free to direct these to the Western Health Office for Research on 83958074 or at: ethics@wh.org.au.

Yours sincerely,

mitim/

Dr Tam Nguyen Manager Western Health Office for Research