



OFFICE FOR RESEARCH E-NEWSLETTER - AUGUST 2024

Office for Research [Website Link](#) and [SharePoint](#)

Consumer Engagement Training Survey

As part of the ACQSHC *Clinical Trials Governance Framework* accreditation process, the Office for Research has engaged a lived experience advisor to assist in the development of a consumer engagement training program.

In order to ensure that the program meets the expectations of our research community we welcome the opportunity for you to participate in a REDCap survey. The survey will assist us in delivering a program that is suited to the needs of our staff. The survey can be accessed via the below link.

<https://survey.wh.org.au/redcap/surveys/?s=A4NWLP74RPLHMFYX>

Research Week 2024

2024 Research Week will be held from 7th - 11th of October.

Research week will comprise of the following sessions. Formal program is currently being finalized.

Monday 7th October 12:30-1:30PM 3:00-5:00PM	OPENING SESSION AIMSS Symposium
Tuesday 8th October 12:30-1:30PM 2:00-4:30PM	Intern Education Allied Health & Chronic and Complex Care
Wednesday 9th October 12:00-2:00PM 12:00-2:00PM 2:00-4:00PM 2:00-4:00PM	Robert Helme, Neuroscience Neville Yeomans, Medicine Geriatric Medicine Oncology
Thursday 10th October 8:00-9:00AM 2:00-4:00PM 4:30-8:00PM	Cardiology Nursing and Midwifery Women's and Children's
Friday 11th October 8:00-12:00PM 8:00-12:00PM 12:30-1:00PM	Robert Smith, Critical Care Kendall Francis, Surgery CLOSING CEREMONY



GRANTS CURRENTLY OPEN FOR WESTERN HEALTH STAFF

The Office for Research in partnership with the Western Health Foundation is proud to announce a number of Research Grants, sponsored by our generous corporate partners BankVic, Maxxia and Plenary Health.

Bank Vic - \$20,000
Maxxia - \$10,000
Plenary Health - \$10,000

These grants can be used to develop a feasibility study or support completion of existing Western Health research initiatives in new models of care, health service delivery, innovation, or quality improvement. You can apply for all three grants for your project if you wish.

[Apply via this link](#)

CLOSING DATE
11:59PM
Sunday 15 Sept 2024

Biostatistical Support at WH



Dr Tanita Botha is available to provide biostatistical support to all WH initiated research. Tanita is assigned to Western Health from Deakin University 2 days a week and is onsite every second Thursday.

All initial general requests for biostatistical support can be made via the email address at statisticalsupport@wh.org.au.

Please complete and submit the following form for all biostatistical support enquiries: [Western Health Biostatistical Support Form](#)



Dr Tanita Botha
WH Biostatistician

OFFICE FOR RESEARCH E-NEWSLETTER - AUGUST 2024

Research Training and Education

The Office for Research is committed to providing ongoing training and workshop opportunities to WH staff. Please access the remaining year's training opportunities via the link: [Research Training Workshop 2024](#).

CLINICAL TRIALS

If you are doing a clinical trial it is required that you complete the below ACTEC module that can be accessed and filed through WeLearn: [ACTEC - Introduction to Clinical Trials](#).

GOOD CLINICAL PRACTICE (GCP) COURSE

We currently do not provide a face-to-face GCP training. It is a requirement that all named investigators on Western Health projects demonstrate current GCP certification. Certifications are valid for 3 years.

Please use the below link for the online training that is required. This is TransCelerate accredited and can be used to demonstrate compliance as part of your governance submission:

[The Global Health Network GCP Online Course](#).

Quality Assurance, Minimal Risk and Low Risk Projects

NHMRC National Statement 2023 (NS 2023)

Please note that the 2007 National Statement was replaced with the 2023 National Statement and the term Negligible Risk is no longer used and has been replaced with Minimal Risk (MR).

Please note that requirements for the ethics review of lower risk projects and the criteria for granting an exemption from ethics review are set out in section 5.1.12 to 5.1.14 and 5.1.17.

Access to the updated NS 2023 can be accessed via the link: [The NS 2023](#).

Please ensure that all research documents (i.e PICF, Protocol or other relevant documents) reference the current NS 2023 and not the revoked NS 2007 as all QA and ethical reviews are conducted against the tenants of the NS 2023.

QA/Minimal Risk & Low Risk Projects via Ethics Review Manager (ERM)

It is a requirement of the Office of Research that all QA, MR and LR project applications are submitted through the ERM link: [The ERM Login](#).

For first time users an account will need to be created via the New User tab on the landing page. In the 'Create Project' window please select the appropriate project 'Form' for QA/MR or low risk ethics and governance review.

- **QA (Quality Assurance) VIC** Form for QA/MR review
- **Low Risk VIC** form for ethics review and
- **Low Risk VIC SSA** for governance review (*created as a sub form to the Low-Risk VIC form*)

You will need to then complete all sections of each of the forms created.

For further assistance with ERM please do not hesitate to contact the Office on the below contact details.

Document Templates (QA/MR and LR)

Please refer to our QA and LR pages on SharePoint and the Western Health Website, Office for Research pages for current and updated templates. (*see below*)

- The Western Health LR and QA/MR Participant Information and Consent Form (PICF) templates are being revised to align with the NS 2023 and will be uploaded later this month.

OFFICE FOR RESEARCH E-NEWSLETTER - AUGUST 2024

- We have two protocol templates available for QA/MR applications. The [QA Clinical Audit Protocol Template](#) June 2024 (now available) and a QA/MR/Evaluation Protocol Template (under review and will be finalized this month).

Post Approval Notifications

- For post approval LR project amendments and reporting a **Sub Form** titled **Low Risk Notification Form** will need to be created for either: Amendment, Progress Report, Site Audit Report or Final Report
- There is no sub-form for post approval notifications for QA projects. For any post approval changes (Change of Personnel/minor administrative change) the correspondence tab within the QA Application must be used. The relevant form for the submission type can be found on the QA pages of our website or SharePoint or contact us directly for guidance and further information.

Mandatory Electronic File Name Convention

The Office for Research has had a mandatory [electronic file naming](#) convention for a considerable time. It is imperative that researchers adhere to the Mandatory File Naming Convention to allow easy identification and review of documents on ERM.

Correctly named documents facilitate a timely review as they make it easier for reviewers to identify the submitted documents. Further, given the letters of SSA Authorisation and Ethics Approval are generated within the ERM system itself, (including the naming format of documents) it makes it easy for researchers to know what documents are listed as approved and/or authorised. Therefore, to reduce unnecessary workload and reduce the timeliness to review and approval we strongly encourage researchers to take the time to label files accordingly.

Failure to comply will result in a request to rectify the file naming discrepancy and delay review timeline

KEY POINTS:

1. Do not use the following symbols in your electronic filename: ! @ \$ % & ?
2. The format outlined below MUST be used for all electronic files submitted for ethics and/or governance review:

Approved Convention:

1. [ERM Project ID] [Document Name] [version number] [Date DDMMYY] e.g., 41234 Protocol v1 01Jan24
2. [name/surname] [document name] [date DDMMYY] e.g., John Smith GCP certificate 01Jan24 or John Smith WH CV 01Jan24

Office for Research Contact Information

We are keen to ensure that we are in a better position to facilitate your research ethics and governance requirements. We appreciate that ethics submissions and governance requirements can seem to be challenging at times, we therefore encourage you to contact the Office for Research and discuss your project research requirements early on in the project cycle.

Research Program Director	Bill Karantasios	bill.karanatsios@wh.org.au
Agreements and General Enquiries	Kai Yan Mak	P: 8395 8070
SSA Governance Submissions	Saritha Bingi	P: 8395 8072
LR Submissions	Deepti Sharma	P: 8395 8069
QA and MR Submissions	Kerrie Russell	P: 8395 8074
Post-Approval & Honorary Appointment	Noami Korboe	P: 8395 8068

Please direct all enquiries to Office of Research staff above subject to area of enquiry.

To Subscribe/Unsubscribe to our monthly e-Newsletter, please send 'Subscribe/Unsubscribe to e-News' in the subject line to research@wh.org.au .