Western Health

Western Health as Study Sponsor for Clinical Trials

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This document is relevant to all WH sites, including Bacchus Marsh, Melton and Caroline Springs

Contents

1. Overview

This document is the procedure for Western Health staff undertaking research who seek to have Western Health act as Sponsor for an investigator initiated clinical research or trial. The WH Office for Research will implement the procedure to determine the capacity of WH to act as a study sponsor.

2. Applicability

This procedure is relevant to all staff at Western Health who wish to explore if Western Health can and should assume the role of sponsor for research that requires a Clinical Trial Notification/Clinical Trial Approval (CTN/CTA) submission to the TGA or for which a CTN/CTA submission requirement is still undetermined.

Clinical Research for which a CTN or CTA requirement is definitively ruled out by the nature of the research will be exempt from this procedure. This determination will form part of the Site-Specific Assessment Process.

3. Responsibility

The Office for Research has the responsibility for introducing and implementing the procedure into operational practice and to ensure that all relevant staff are aware of their obligations in compliance with this procedure.

4. Authority

Exemptions to the practices described in this procedure can be authorised by the Research Program Director/Director of Clinical Research, Manager Office for Research and/or the Chief Medical Officer.

5. Associated Documentation

In support of this procedure, the following Manuals, Policies, Instructions and/or Guidelines apply:

- WH Research, Ethics and Governance Policy
- WH Research, Ethics and Governance Procedure
- WH Clinical Trial Governance Framework 2023
- WH Standard Operating Procedures – Good Clinical Practice (GCP)

6. Credentialing Requirements

Not Applicable

7. Procedure Detail

All trials that require WH to be the study sponsor will need to be considered by the WH Office for Research prior to submitting for ethics and governance review and approval. Investigators need to follow the processes outlined below to apply for study sponsorship from WH:

1) Investigator will need to complete the REDCap survey "Clinical Trial WH as Sponsor Assessment Tool" for risk assessment and send the latest draft of the study protocol to WH Office for Research at ethics@wh.org.au for review.
2) Research Program Director/Director of Clinical Research/Manager Office of Research and/or the Chief Medical Officer will review the assessment tool and the protocol and may request a meeting to discuss the details of the trial.
3) Studies that are determined by the REDCaP Assessment Toolkit to not necessitate a CTN/CTA submission can proceed to ethics and governance submission and authorisation.
4) If any revisions/concerns are recommended, investigator must address these and re-submit the revised documents to WH Office for Research for further review.
5) Research Program Director/Director of Clinical Research/Manager Office for Research and/or the Chief Medical Officer will discuss the project, determine the degree of oversight required and plans/recommendations for monitoring and decide the review outcome.
6) The WH Office for Research will notify the investigators of the review outcome via an email.
7) Investigator can then proceed with the ethics and governance application for the trial once the WH sponsorship status has been confirmed.
8) WH as the sponsor and study investigator are obligated to ensure that all study personnel are familiar with the role and obligations of sponsor in the conduct of the study and that they undertake any requisite training to ensure

compliance with ICH GCP requirements. Governance authorisation will be contingent on demonstrating suitable compliance in this regard.

9) WH as the sponsor and study investigator are obligated to monitor the study in compliance with the NHMRC, TGA and WH trial monitoring and risk management guidelines. As such WH sponsored studies will be more likely to be prioritised for auditing by the WH Office for Research.
10) If investigator decides to make amendments to the study that may substantially impact the risk assessment after WH sponsorship approval, they will be firstly reviewed by the sponsor and investigator must address any sponsor's concerns prior to ethics and governance amendment submission.
11) Of note while the investigator holds the primary responsibility for determining whether the amendment substantially changes the risk of a trial, the sponsor (WH Office for Research) reserves the right to reject the amendment if that the proposed amendment is deemed to substantially changes the trial's risk.
12) The investigator must hold an annual meeting with the sponsor (WH Office for Research) to discuss the study progress including recruitment, data collection/analysis, study monitoring, risk management and etc. The date of the annual meeting will be determined by the WH Office for Research (most likely 12 months from the date of the local governance approval).

8. Document History

Number of previous revisions: New Document

Previous version dates: Not applicable to this version

Minor amendment: Not applicable to this version

9. References

- Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice ICH E6 (2) 2016 – Annotated with TGA comments available at https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
- Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95) annotated with TGA comments at https://www.tga.gov.au/sites/default/files/ich37795.pdf
- TGA Guidance: Australian Clinical Trial Handbook: Guidance on conducting clinical trials in Australian using "unapproved" therapeutic goods, Version 2.4 August 2021, available at https://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook.pdf
- NHMRC The National Statement on Ethical Conduct in Human Research 2023 available at National Statement on Ethical Conduct in Human Research 2023 | NHMRC.
- NHMRC Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods 2016 available at https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods
- Department of Health and Human Services Victoria, Coordinating Office for Clinical Trial Research Information on requirements for trials available at can be found in "Research governance and Site specific assessment – process and practice" available at https://www.clinicaltrialsandresearch.vic.gov.au/__data/assets/pdf_file/0020/171146/Research-Governance-SSA-Process-and-Practice.-March-2024.pdf

10. Sponsor

Research Program Director, WH Office for Research

11. Authorisation Authority

Chief Medical Officer, Western Health