Western Health

STANDARD OPERATING PROCEDURE

Documentation of Investigational Site Qualifications, Adequacy of Resources and Training Records

Standard Operating Procedure

Western Health

SOP reference	001
Version	3.0 dated June 2019
Effective Date	June 2019
Review Date	June 2021
Approved/Endorsed by:	Mr Bill Karanatsios, Research Program Director
Signature and date	

Amendment History

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated and aligned with MACH SOPs

1. PURPOSE

To describe the procedures related to the appropriate documentation of investigational site qualifications and training records as well as the provision of resources to perform research appropriately.

2. SCOPE

This standard applies to all Western Health (WH) employees who propose to undertake, administrate, review and/or govern human research in their capacity as a WH employee.

3. APPLICABILITY

Principal Investigator, Associate Investigator(s), research co-coordinators and other staff delegated to research related activities at WH.

4. PROCEDURE

For investigator initiated trials where WH is also the sponsor, obligations owed to or emanating from sponsor should be interpreted to mean WH.

1. Documentation of Investigational Site Qualifications and Training Records

The investigator(s) should:

STEP	ACTION
4.1.1	Maintain an up-to-date Curriculum vitae (CV) and review with an updated signature and date on a yearly basis.
4.1.2	Be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial. This should be evidenced in the CV.
4.1.3	Meet all the qualifications specified by the applicable regulatory requirement(s). Current medical practitioner registration details and similar documentation should be referenced in the CV.
4.1.4	Provide evidence of such qualifications through up-to-date CV and/or other relevant documentation requested by the Sponsor, the Human Research Ethics Committee (HREC), Research Governance Office (RGO), and/or the regulatory authority(ies).
4.1.5	a) For Clinical Trials, ensure that all principal investigators, associate investigators and trial coordinators of research studies hold a current TransCelerate mutually recognised Good Clinical Practice (GCP) certification. b) For non-clinical trials, ensure that the principal investigator hold a current TransCelerate mutually recognised Good Clinical Practice (GCP) certification. A copy of the GCP course certificate valid for 3 years from completion should be included with the research governance application.
4.1.6	Maintain a list of appropriately qualified persons to whom the investigator has delegated significant research related duties. The list is in the form of a Delegation Log and delegated duties should be captured and signed and dated by the investigator on a per person basis. The delegation log may be

	provided by the Sponsor company but for investigator-initiated studies, refer to the WH delegation log (See Appendix 1).

2. Adequacy of Resources

The investigator(s) should:

STEP	ACTION
4.2.1	Be able to demonstrate (if possible based on retrospective data) a potential for recruiting the required number of suitable participants within the agreed recruitment period. This may be in the form of coded re-identifiable/non-identifiable participant recruitment listings or other documented written evidence.
4.2.2	Have sufficient time to properly conduct and complete the project within the agreed project period and have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the project to conduct the study properly and safely.
4.2.3	For all studies, the adequacy of resources is normally determined by a site feasibility assessment. A Site Specific Assessment should be conducted to fulfil this role.
4.2.4	Submit and obtain Site Specific Assessment (SSA) Governance Authorisation from the Office for Research prior to commencement of research. The SSA Governance Application includes explicit resource declarations from departments involved in the planned project.

3. Training Records

The investigator(s) must:

STEP	ACTION
4.3.1	Ensure that all persons assisting with the project are adequately informed about the protocol, the investigational product(s), and their study-related duties and functions. An initiation meeting should be held where all required staff are present and written evidence that the initiation meeting is held and evidence that study specific training is developed (Appendix 2 & 3).
4.3.2	Ensure that documentation of this training be kept current and available for review on request throughout the entire project period (Appendix 2 & 3).
4.3.3	Ensure that tasks delegated to study staff are documented appropriately. This can be evidenced by the delegation log. Study specific training records should be maintained to provide evidence that all tasks were delegated following the correct training (Appendix 1, 2 & 3).

5. GLOSSARY

Appropriately Qualified Persons

Person/s qualified by professional qualifications, currently registered to practice in the field and operating within the delegated persons Professional Scope of Practice

Associate Investigator

Any individual member of the clinical trial team designated and supervised by the investigator at a study site to perform critical study-related procedures and/or to make important study-related decisions (e.g., associates, residents, research fellows). Also referred to as "Sub-Investigator".

Clinical Research Coordinators

A research worker who works at a clinical research site under the immediate direction of a Principal Investigator, whose research activities are conducted under Good Clinical Practice guidelines. May also be called "Clinical Trial Coordinator", "Research Coordinator" or "Study Coordinator".

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

Human Research Ethics Committee (HREC)

A body which reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.

The National Statement requires that all research proposals involving human participants be reviewed and approved by an HREC and sets out the requirements for the composition of an HREC.

International Conference on Harmonisation (ICH)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs.

Investigator initiated trial

A clinical trial that is undertaken by the investigator whereby the investigator and/or their institution takes on the role of the sponsor in addition to their role as investigator.

Principal Investigator (PI)

An individual responsible for the conduct of a clinical trial at a trial site ensuring that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the Principal Investigator. In this instance they may delegate tasks to other team members.

Research Governance Office (RGO)

Site/institutional office that are accountable for the research activities conducted at their site to ensure that research is conducted according to established ethical principles, guidelines for responsible research conduct, relevant legislation and regulations and institutional policy.

Site Specific Assessment (SSA)

A Research Governance application/Site Specific Assessment (SSA) is a key element of research governance.

Sponsor

An individual, company, institution or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.

TransCelerate

TransCelerate BioPharma Inc. was launched in 2012 as a non-profit organization that collaborates across the global biopharmaceutical research and development community to identify, prioritise, design and facilitate implementation of solutions designed to drive the efficient, effective and high quality delivery of new medicines.

6. REFERENCES

1. Based on VMIA GCP SOP No.001 Version:1.0 Dated 17 September 2007
2. Based on MACH GCP SOP No.001 Version 1.0
3. Note for guidance on Good Clinical Practice (CPMP/ICH/135/95) annotated with TGA comments DSEB, July 2000.
4. National Statement on Ethical Conduct in Human Research (2007)
5. http://www.transceleratebiopharmainc.com/assets/site-qualification-and-training/

7. APPENDICES

Appendix 1: Template for Signature and Delegation Log

Appendix 2: Training Register

Appendix 3: Template for Internal Training Record

Appendix 4: WH Investigator Curriculum Vitae Template

8. AUTHORS/CONTRIBUTORS

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9. PRIMARY PERSON/DEPARTMENT RESPONSBLE FOR DOCUMENT

Western Health Office for Research

APPENDIX 1: SIGNATURE LOG AND DELEGATION OF DUTIES (TEMPLATE)

SOP No.001 Appendix 1 Version 3.0 Dated May 2019

SIGNATURE LOG AND DELEGATION OF DUTIES (template)

	Protocol No:	
	Investigator Name:	
	Sponsor:	

Start Date Of Involvement	Print Name	Signature	Sample Initials	Function (e.g. sub-investigator, study nurse)	Task Delegated	Authorised by Investigator (initial+ date)	End date of Involvement

a. Informed discussion
b. Informed consent sign off (PI or Sub PI Only)
c. CRF/DCF Completion and Correction
d. CRF/DCF Sign-Off
e. Participant Examination/evaluation
f. Investigational product dispensation
g. Investigational product accountability
h. Randomization of participants (e.g. IVRS)
i. Essential / Regulatory documents handling
j. Study specific procedures
k. Other

APPENDIX 2: WH TRAINING REGISTER

SOP No.001 Appendix 2 Version 3.0 Dated May 2019

TRAINING COURSE: _____

DATE	EMPLOYEE NAME	TRAINER	CONTENT	CERTIFICATE Y/N

PI SIGNATURE: _____ DATE: _____

Western Health

Internal Training Record

Section 1 – Employee (Trainee) Details

Name :		**Position /Title :**	

Section 2 – Training Details

Date(s) of Training :		**Duration :**	
Type :	Classroom ☐ eLearning ☐ Other ☐ *(Provide details in Description section)*		
Location :			
Description :			
SOP / Module /Course : (If applicable)		**Version :**	
Trainer Name :		**Title :**	

Section 3 –Competency Assessment / Sign Off

Do not sign unless you are confident you understand the implications of the training conducted.

Trainee Comments

_____

_____

_____

_____

Employee (Trainee) :	_____ *Signature or Initials*	**Date:**	____/____/_____ *dd/mmm/yyyy*

Trainer Comments (describe competency assessment if applicable)

_____

_____

_____

_____

Trainer :	_____ *Signature or Initials*	_____ *Title*	**Date:**	____/____/_____ *dd/mmm/yyyy*

APPENDIX 4: WH INVESTIGATOR CURRICULUM VITAE

WH Curriculum Vitae Template Version 5 Dated August 2018

Western Health Investigator Curriculum Vitae		
Title, First and Family Name:		
Present appointment: (Job Title, Department)		
Address: Full work address including postcode		
Qualifications: Degree and other professional qualifications (☒ relevant qualifications, or specify)	PhD: ☐ MBBS: ☐ MSc: ☐ BN: ☐ BSc: ☐ Other: Please state date and location of where qualifications were obtained:	
AHPRA Registration number: (or equivalent)		
Previous appointments/ Experience: (Include only relevant therapeutic/ practical experience after gaining qualifications)		
Publications: (☒ appropriate box) (Number of articles published)	0 ☐ 1-2 ☐ 3-5 ☐ 6-10 ☐ 11-20 ☐ ›20 ☐	
Previous research experience: ☐ Clinical Trial Research – Drug/Device ☐ Clinical Research – non-drug ☐ Health and Social Science ☐ Quality Assurance/Improvement ☐ Other – please specify:	☐ Protocol design ☐ Recruitment ☐ Consent ☐ Data collection	☐ Data management ☐ Trial procedures ☐ Other - please describe below:
Training: (accredited courses) Please attach and provide evidence of training i.e. certificates	☐ GCP ☐ Research Ethics ☐ Research Conduct	☐ No Training ☐ Other - please describe below:
List all/attach a list of projects that you held or currently hold the role of investigator (Principal and/or Associate):		
I, have read and agree to comply with the Western Health Research Code of Conduct [2018].		
Signature	Date	