

<b>MELBOURNE HEALTH</b>	<b>OFFICE FOR RESEARCH</b>		
	<b>STANDARD OPERATING PROCEDURE: SOP001</b>		
	<b>Documentation of Investigational Site Qualifications, Adequacy of Resources and Training Records</b>		
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## 1. AIM

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

Applicable to all clinical research projects undertaken at Melbourne Health, including investigator initiated research, collaborative research and all phases of clinical investigation of medicinal products, devices and diagnostics.

## 3. APPLICABILITY

This SOP applies to all Principal Investigators, Sub-Investigator(s), research co-coordinators and other staff involved in clinical research at Melbourne Health.

## 4. PROCEDURE

### 4.1 Documentation of Investigational Site Qualifications and Training Records

**The investigator(s) should:**

- Ensure that the *Curriculum vitae* (CV) of each research staff on the project are current and are signed and dated by the researcher at the start of a study. Refer to the Office for Research website for an example of a CV template.
- Maintain an up-to-date CV. CVs are to be updated when there is a change that is relevant to the research project such as updated training information.
- Be qualified by education, training, and experience to assume responsibility for the proper conduct of the research. This should be evidenced in the CV and training record and must include evidence of ICH GCP training (as specified in MH SOP 010 section 4.1) for the researchers and coordinators undertaking clinical trial studies. ICH GCP training is also recommended for other researchers but is not mandatory unless specified by the Office for Research for particular researchers/projects.

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- 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.
- Provide evidence of such qualifications through up-to-date *Curriculum vitae* and/or other relevant documentation requested by the sponsor, the HREC, and/or the regulatory authority(ies).
- Maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-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. Where there is an external Sponsor, the delegation log may be provided by the Sponsor Company. For investigator-initiated studies, use the Signature and Delegation in Appendix 2.

## 4.2 Adequacy of Resources

### The investigator(s) should:

- Be able to demonstrate (if possible based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period. This may be in the form of de-identified subject recruitment listings or other documented written evidence.
- Have sufficient time to properly conduct and complete the trial within the agreed trial period and have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.
- Adequacy of resources are normally determined by a site feasibility assessment for commercially-sponsored studies. However, PI's of other research studies, i.e. investigator initiated or collaborative group studies, must also consider the adequacy of resources when submitting project applications.
- Submit and receive approval of the Site Specific Assessment/Governance Application from by the Office for Research prior to commencement of research at Melbourne Health. The Site Specific Assessment/Governance Application includes budget sign-off from the Office for Research Management Accountant Research (MAR) and explicit resource declarations (Statements of Approval etc) from departments involved in the planned study.

## 4.3 Training Records

### The investigator(s) should:

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Melbourne Health SOP No. 001 (based on VMIA SOP No. 001)

**DOCUMENTATION OF INVESTIGATIONAL SITE QUALIFICATIONS, ADEQUACY OF RESOURCES AND TRAINING RECORDS**

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Review Date: May 2020

Effective Date 1 May 2017

- Ensure that all persons assisting with the research project are adequately informed about the protocol and their research-related duties and functions. Where the research is a clinical trial, all persons assisting with the research project must also be adequately informed about the investigational product(s). An initiation meeting may be held where all required staff are present and written evidence of study specific training is developed.
- Ensure that documentation of this training be kept current and available for review on request throughout the entire research period.
- Maintain current certified GCP training if involved in clinical trials at Melbourne Health or where specified by the Office for Research for particular researchers/projects. To meet OfR requirements the GCP training must be recognised by the certification process that TranCelerate Biopharma INC has implemented to recognise GCP training courses that contain material [meeting the minimum criteria agreed to by its member organizations \(pharma companies\)](http://www.transceleratebiopharmainc.com/wp-content/uploads/2013/10/TransCelerate-GCP-Training-Minimum-Criteria-in-Operating-Principles_0.pdf). For details of the criteria refer to [http://www.transceleratebiopharmainc.com/wp-content/uploads/2013/10/TransCelerate-GCP-Training-Minimum-Criteria-in-Operating-Principles\\_0.pdf](http://www.transceleratebiopharmainc.com/wp-content/uploads/2013/10/TransCelerate-GCP-Training-Minimum-Criteria-in-Operating-Principles_0.pdf)
- Ensure that tasks delegated to study staff are documented appropriately. This can be evidenced by the delegation log. However, study specific training records should be maintained to provide evidence that tasks were delegated following the correct training.

## 5. GLOSSARY

### **Good Clinical Practice (GCP)**

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, 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 subjects 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.

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## Investigator

An individual responsible for the conduct of a research projects including clinical trials at a research/trial site and ensures that it complies with GCP guidelines. If a research/trial is conducted by a team of individuals at a research/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.

## Sub Investigator

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

## 6. REFERENCES

1. MH Research Policy MH18
2. Note for guidance on Good Clinical Practice (CPMP/ICH/135/95) annotated with TGA comments DSEB, July 2000.
3. National Statement on Ethical Conduct in Human Research, (2015).

## 7. APPENDICES

- Appendix 1: SOP Change Log
- Appendix 2: Template for Signature and Delegation Log
- Appendix 3: Example Training Record Form
- Appendix 4: Example Curriculum Vitae Template

### APPENDIX 1 : SOP CHANGE LOG

<b>Version No.</b>	<b>Reason for Issue</b>
1	First issue
2	26/9/2013 Updated to specify PI's CVs must record ICH GCP training
3	27/2/2017 Review and update

**DOCUMENT END**

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## APPENDIX 2: SIGNATURE LOG AND DELEGATION OF DUTIES (TEMPLATE)

SIGNATURE LOG AND DELEGATION OF DUTIES (template)							
	Protocol No:			Local HREC/Research Governance Approval 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 (PI) (initial+ date)	End date of Involvement
a. Informed discussion b. Informed consent sign off c. CRF/DCF Completion and Correction d. CRF/DCF Sign-Off e. Subject Examination/evaluation f. Investigational product dispensation					g. Investigational product accountability h. Randomization of subjects (e.g. IVRS) i. Essential / Regulatory documents handling j. Study specific procedures k. Other		