Austin Health

OFFICE FOR RESEACH
PROCEDURE

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

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:

Applicable to all phases of clinical investigation of medicinal products, devices and diagnostics, inclusive of Industry Sponsored, Collaborative Group or Investigator Initiated trials.

3. Staff this document applies to:

Principal Investigator, Associate Investigator(s), research co-coordinators and other staff involved in trial-related duties.

4. Procedure:

4.1 Documentation of Investigational Site Qualifications and Training Records

The investigator(s) should:

- Maintain an up-to-date *Curriculum vitae* (CV) and review with and updated signature and date on a yearly basis
- Be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial. This should be evidenced in the CV.
- 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).
- Austin Health requires that all principal investigators, associate investigators and trial coordinators of research studies hold a current TransCelerate mutually recognised good clinical practice (GCP) certification.[4] A copy of the GCP course certificate valid for 3 years from completion should be included with the research governance application.
- 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 Principal Investigator on a per person basis. The delegation log may be provided by the Sponsor Company, but for Investigator Initiated studies, a separate site log should be developed (see Appendix 2).

** *"Appropriately qualified persons" means qualified by professional qualifications, currently registered to practice in this field and operating within the delegated persons Professional Scope of Practice (eg Doctor for prescribing of study medication or Pharmacist/Clinical Research Coordinator for dispensing study medication)*

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.
- For commercially-sponsored studies the adequacy of resources is normally determined by a site feasibility assessment.
- Submit and receive approval of the Site Specific Assessment/Governance Application from the Office for Research prior to commencement of research at Austin Health. The Site Specific Assessment/Governance Application includes explicit resource declarations from departments involved in the planned study.

4.3 Training Records

The investigator(s) should:

- Ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions. An initiation meeting must 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 trial period.
- 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.

Glossary

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" or "Research Coordinator". (ARCP Definition.)

Good Clinical Practice (GCP): From the International Conference on Harmonisation (ICH) guidance, GCP is 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.

Principal Investigator: 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.

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

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, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high quality delivery of new medicines.

Legislation/References/Supporting Documents:

1. Based on, and with permission of the Victorian Managed Insurance Authority – VMIA GCP SOP No.001 Version:1.0 Dated 17 September 2007
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, (2007).
4. http://www.transceleratebiopharmainc.com/assets/site-qualification-and-training/

Appendices

Appendix 1: Template for Signature and Delegation Log

Appendix 2: Example Training Record Form

Appendix 3: Example Curriculum Vitae Template

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TBC

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

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
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

APPENDIX 2 : INTERNAL TRAINING LOG (TEMPLATE)

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 3: CURRICULM VITAE (TEMPLATE)

Austin Health

Austin Health Investigator Curriculum Vitae

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 ☐ BN ☐ MSc ☐ BSc ☐ Other:
Registration/licence number (if applicable)	
Previous appointments/ experience (include only relevant therapeutic/ practical experience after gaining qualifications)	
Publications (✓ appropriate box) (Number of articles published)	0 ☐ 0–5 ☐ 6-10 ☐ 11-20 ☐ >20☐
Previous experience in clinical trials	☐ Protocol design ☐ Recruitment ☐ Consent ☐ Data collection ☐ Data management ☐ Trial procedures ☐ Other – please describe below:
Training (accredited courses)	☐ GCP ☐ Research Ethics ☐ Research Conduct ☐ Other – please describe below:
List all HREC projects that you currently hold the role of investigator (Principal and/or Associate	

Signature: .....

Date: .....