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

Standard Operating Procedure

Office of Health and Medical Research
Queensland Health

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Author: Katrina Brosnan
Approved by: Dr Jane Jacobs, Director, Research Ethics and Governance Unit

Amendment History

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Based on, and with permission of the Victorian Managed Insurance Authority – VMIA GCP SOPS
Reviewed by the QH Clinical Research Coordinators Network May 2010
1 Purpose

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

2 Responsibility / Scope

This standard applies to all Queensland Health employees (including visiting medical officers, visiting health professionals, contractors, consultants and volunteers) who propose to undertake, administrate, review and/or govern human research involving Queensland Health patients and staff.

3 Procedure

3.1 Documentation of Investigational Site Qualifications and Training Records

The investigator(s) must:

- Maintain an up-to-date Curriculum vitae (CV) and submit to the site Governance Office at the site every 2 years. **QH RGO SOPS 1.10.3**
- Be qualified by education, training, and experience to assume responsibility for the proper conduct of the research. This should be evidenced in the CV. **ICH GCP 4.1**
- Meet all the qualifications specified by the applicable regulatory requirement(s). Current medical practitioner registration details and/or similar documentation should be referenced in the CV. **ICH GCP 4.1**
- Provide evidence of such qualifications through up-to-date CV and/or other relevant documentation requested by the sponsor, (eg current GCP training) the HREC, and/or the regulatory authority(ies). **ICH GCP 4.1**
- 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 but for investigator-initiated studies, a separate site log should be developed. The log should record sample signatures, initials of the investigators and, if required, record the numbers 0-9 for each person. **ICH GCP 4.1**

** “ 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 Pharmacist or Doctor for dispensing of study medication and Doctor or Registered / Endorsed Enrolled Nurses for administration of study medication, OR holding a current “Biological Substances, Category B and/or Dangerous Goods” certificate in order to ship those substances).
3.2 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 participants within the specified recruitment period. This may be in the form of de-identified participant recruitment listings or other documented written evidence. ICH GCP 4.2
- Have sufficient time to properly conduct and complete the research within the specified period and have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the research to conduct the project properly and safely. ICH GCP 4.2
- For commercially-sponsored studies, the adequacy of resources is normally determined by a site feasibility assessment.

3.3 Training Records

The investigator(s) should:

- Ensure that all persons assisting with the research are adequately informed about the protocol, any investigational product(s), and their research-related duties and functions. ICH GCP 4.2.4
- Ensure an initiation meeting is held where all required staff are present and written evidence of study specific training is documented. ICH GCP 8.2.20
- Ensure that documentation of this training be kept up to date and available for review on request throughout the entire duration of the project. ICH GCP 8.2.20
- Ensure that tasks delegated to study staff are documented appropriately. This can be evidenced by the delegation log. However, project specific training records should be maintained to provide evidence that tasks were delegated following the correct training.

4 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.)

Human Research Ethics Committee (HREC)
A body which reviews research proposals involving human participants to ensure that they are ethically and scientifically 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.

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

**QH RGO SOPS**


**Research Governance Office(r) / Function**

The Office or coordinated function within a Public Health Organisation which is responsible for assessing the site-specific aspects of research applications, make a recommendation to the District CEO / delegate as to whether a research project should be granted authorisation at that site, and overseeing that authorised research at the site meets appropriate standards (research governance).

**Sub / Associate Investigator**

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows, clinical research coordinators. The P.I. will designate who will be nominated as Associate Investigators for that site.

## 5 Appendices

- **Appendix 1:** Template for Signature and Delegation Log (word doc)
- **Appendix 2:** Example Training Record Form (word doc)
- **Appendix 3:** Example Curriculum Vitae Template
Appendix 1:

**SIGNATURE LOG AND DELEGATION OF DUTIES**

<table>
<thead>
<tr>
<th>Protocol No:</th>
<th>Site Name and Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator Name:</td>
<td></td>
</tr>
<tr>
<td>Sponsor:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Print Name</th>
<th>Signature</th>
<th>Sample Initials</th>
<th>Sample numbers if required</th>
<th>Function (e.g. P.I.)</th>
<th>Task Delegated</th>
<th>Authorised By P.I. (initial+ date)</th>
<th>Start Date Of Involvement</th>
<th>End date of Involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Project Staff Function Codes:**

<table>
<thead>
<tr>
<th>Function Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CI</td>
<td>Coordinating Investigator</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>AI / SI</td>
<td>Associate/Sub Investigator</td>
</tr>
<tr>
<td>SC</td>
<td>Study Coordinator</td>
</tr>
<tr>
<td>RA</td>
<td>Research Assistant</td>
</tr>
<tr>
<td>Other (please nominate)</td>
<td></td>
</tr>
</tbody>
</table>

**Delegated Tasks Codes:**

- 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 dispensing
- g. Investigational product accountability
- h. Randomisation of subjects (eg IVRS)
- i. Essential / regulatory documents handling
- j. Study specific procedures
- k. Other (eg vital signs measurement, collation and faxing of SAE’s and other study documentation etc)

Principal Investigator Signature: ____________________________ Date: ____________________________

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Prepared by the Research Ethics and Governance Unit | May 2010
Based on, and with permission of the Victorian Managed Insurance Authority – VMIA GCP SOPS
Reviewed by the QH Clinical Research Coordinators Network May 2010
# Appendix 2

## Internal Training Record

### Section 1 – Researcher Details

<table>
<thead>
<tr>
<th>Name</th>
<th>Position / Title</th>
</tr>
</thead>
</table>

### Section 2 – Training Details

<table>
<thead>
<tr>
<th>Date(s) of Training</th>
<th>Duration</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Type</th>
<th>Classroom</th>
<th>eLearning</th>
<th>Other</th>
<th>(Provide details in Description section)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Location</th>
<th>Description</th>
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</table>

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<tr>
<th>SOP / Module</th>
<th>Version</th>
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</table>

| (If applicable) | |

<table>
<thead>
<tr>
<th>Trainer Name</th>
<th>Title</th>
</tr>
</thead>
</table>

### 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

Guidance Document for Curriculum Vitae’s.

- The Curriculum Vitae (C.V.) should be signed and dated by the subject of the CV.
- CV’s should be 1-2 pages in length.
- Summary information should be supplied in the CV. If necessary, greater detail may be attached as an appendix to the document for optional perusal by the reader.
- If the CV is used for a commercially sponsored clinical trial, where an FDA 1572 form is used, the name of the investigator must be exactly the same on the CV as it is on the FDA 1572. The details of the institution must also be exactly the same on the CV as on the FDA 1572.
- Date of Birth, private address and other details of a personal nature are not required.

The following items should be covered in the CV:

Personal Details:
- Subject Full Name
- Address of Employing Institution
- Professional Contact details of CV Subject
- Registration details.

Professional Details:
- Professional education qualifications including place and date of qualification
- Relevant post graduate qualifications including dates and names of institutions (full details may be provided as an Appendix to the main document if desired)
- Professional experience, past and present (ensure the current appointment place is the same as on the 1572).
- All major gaps in working experiences should be explained eg maternity leave

Research Details:
- Relevant research experience including the roles undertaken, the number of studies and therapeutic area. (If necessary, full details may be provided as an Appendix to the main document).
- Relevant research-related training undertaken in the last two years, and the dates of that training should also be included eg GCP training (including a description of the topics covered), or training for study specific procedures. A comprehensive list of all research-related training may be added as an appendix to the document, including the types of eCRF that have been used.

The headers below may be used to create/guide the CV:

Name:

Subject Professional Address

Contact details: include postal address (P.O. Box not allowed) telephone, email and fax details)

Registration type and number: attach copy of registration if requested

Education: tertiary qualifications only, including institutions and dates

Post graduate qualifications: include institutions and dates

Professional Experience: include previous and current employment details

Research Experience: include the type of research, therapeutic area, number of research studies and the role undertaken

Research related training: include GCP training, eCRF training including database name, and other specific study related training and the dates of that training (these may be included as an Appendix, if preferred)

Signature and Date.