

ARTIC PC WPD GCP and research CVs

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1. Introduction, Background and Purpose

The local PI as a minimum should have current, within 2 years, GCP. All recruiting staff should provide current research CVs for projects to which they are involved, including administrative support staff.

2. Abbreviations

See Reference Document: CRN Glossary of Terms and Abbreviation.

3. Scope

This WPD refer to all staff involved in research projects.

4. Responsibilities

The sponsor or delegated individual should establish who is required to provide evidence of GCP.

5. Procedures

5.1 The evidence of GCP

- The PI and any other individual for whom it is decided) should provide a copy of their current GCP certificate for the TMF. A copy should be kept in each project's ISF.

5.2 Research CVs

- A signed and dated CV should be provided for the TMF. The template document provided in the Ethics application documents is sufficient for sites.
- A wet ink signed and dated research CV should be in the site ISF.
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5.3 Training records – project specific

Any training undertaken for a research project should be documented on a project specific training log which is linked to a signature and delegation log.

6. Related SOPs, Work Instructions and Documents

6.1 SOPs

None

6.2 Working Practice Documents

None

6.3 Reference Documents

Declaration of Helsinki
ICH Good Clinical Practice (GCP)
EU Clinical Trials Directive
Research Governance
CRN Glossary of Terms and Abbreviations
Research Ethics Committees and IRAS
Incident and near miss reporting
Indemnity arrangements
Registering with the Information Commissioner's Office