

Title: Good Clinical Practice/Good Research Practice training

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Document History

Version	Description of update	Date Effective
1	Change of number for Q-Pulse	2-10-15
2	Removal of requirement to detail GCP training in CV, in addition to retaining certification in TMF and training record	1-9-16
3	Reformatted and minor changes to wording	1-4-17
4	Reference UK Policy Framework for Health & Social Care Research at 2.3	1-6-18
5	Change of title to include Good Research Practice Changes to scope at 1.2, 1.3, and 1.4. Change to responsibilities at 2 Revised procedure at 3. GRP and the local GRP training course added at 2.1 and 3.11, respectively. Updated Abbreviations and Definitions at 4 Updated Related Documentation and References at 5	5-11-18
6	Reference to GRP at 2 and 3.14. Updated course reference at 1.3	6-1-22

1. Scope

1.1 This SOP applies to University of Aberdeen (UoA) and NHS Grampian (NHSG) researchers and staff undertaking studies involving human participants; healthy volunteers, patients and staff, (including tissue and data).

1.2 Everyone involved in the conduct of clinical research must have training to ensure they are best prepared to undertake their responsibilities.

1.3 Good Research Practice (GRP) in NHSG and the UoA is a local course specifically designed for researchers working on non-drug studies (previously known as Good Research Practice for Health Care Research (non-drug)). It references the UK Policy Framework for Health & Social Care Research and is underpinned by the principles of ICH Good Clinical Practice (GCP).

1.4 The regularity of GCP is not defined in the legislation. This SOP covers the frequency of GCP training (CTIMP) or GRP training (non-drug) required by NHSG and UoA.

2. Responsibilities

Research Governance Team
Chief/Principal Investigator (CI/PI)

Check CI has valid GCP/GRP training prior to sponsorship.
Ensure study team have evidence of relevant, up-to-date GCP/GRP training, commensurate with their role in the study, and are listed on the delegation log where appropriate.

NHSG Training Team

Ensure local and on-line GCP/GRP training courses are available to researchers.

R&D Permission


Check whether PI has valid GCP/GRP training prior to permission. If not present, notify Training Team.


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2.1 NHSG and UoA have the responsibility for developing and promoting a high quality research culture and for ensuring that staff employed in research are supported in, and held to account for, the professional conduct of research. This is enabled by requiring that research staff undergo GCP/GRP training at a level commensurate with their role.


2.2 Researchers are also required to maintain awareness of current standards through reference to published guidance, relevant policies and legislation.


2.3  Research staff in both NHSG and UoA undertaking studies which involve human participants; healthy volunteers, patients, staff, (including their tissue and clinical data) agree to abide by the principles of the UK Policy Framework for Health & Social Care Research.


2.4  For Clinical Trials of Investigational Medicinal Products (CTIMPs) adherence to the principles of GCP is incorporated into UK legislation. The UK Clinical Trials Regulations (SI 2004/1031), as amended, states that no person shall conduct a clinical trial otherwise than in accordance with the conditions and principles of GCP (Reg 28) and that each individual involved in conducting a trial shall be qualified by education, training and experience to perform these tasks (Schedule 1, Part 2, 8).

3. Procedure

Category 1: CTIMPs or Medical Device Clinical Investigations (MDCIs)


3.1  NHSG and UoA require that evidence of attendance/certification at a recognised GCP training* course for CTIMP research is updated every two years, or after major changes in clinical trial legislation (whichever occurs first).

3.2  For both sponsored and hosted studies, staff working on the study shall be named on a Delegation Log (where appropriate). Documented evidence of GCP training, commensurate with the role they have in the study, shall be available.

3.3  If a research activity is part of a person's normal clinical role and all other protocol activities are undertaken by a member of the research team, then no GCP training may be required, however this should be confirmed with the Sponsor.


Sponsorship

3.4 For research involving CTIMPs or MDCIs, and sponsored or co-sponsored by NHSG and/or UoA, evidence of valid GCP training for the CI and any local co-investigators shall be checked upon receipt of application for sponsorship. If no valid evidence is available, the CI shall be directed to the Training Team who will offer appropriate training courses.

3.5  Sponsorship of new CTIMPs or MDCIs may be given if the CI does not have valid GCP training, but is required to be in place **prior** to Site Initiation Visit (SIV).

3.6  GCP training shall be checked during monitoring visits to ensure it is kept up-to-date (see 3.1).

3.7 For locally sponsored multi-centre studies it is the responsibility of the CI, or delegate, to ensure that the PI and all relevant research staff at sites have suitable GCP training and evidence available. If the PIs at sites do not comply, the CI or delegate must escalate the non-compliance to Sponsor.

 The frequency of these updates may be dictated by local site policy outwith NHSG or UoA and should be documented in the Trial Master File and/or Investigator Site File accordingly.


R&D permission

3.8 For research involving CTIMPs or MDCIs, sponsored either locally or externally, evidence of valid


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GCP training for the PI shall be checked upon receipt of application for R&D Permission. If no valid evidence is available, the PI shall be directed to the Training Team who offer appropriate training.

3.9  R&D Permission shall not be withheld if there is no valid GCP training at the time of permission, but the Sponsor shall be informed so that a decision can be made regarding study commencement.

Quality Assurance

3.10  If during the course of monitoring or audit, poor research practice is noted in locally sponsored or hosted studies, GCP or other targeted training shall be offered to the CI/PI. If training is not undertaken, the Quality Assurance team shall escalate this to the Sponsor of the study and Clinical Studies Oversight Group (CSOG), if necessary.

***Please contact the Training Team in the R&D office to confirm recognised GCP courses.**

Category 2: Any other studies

3.11 NHSG and UoA **highly recommend** that evidence of attendance/certification at the local GRP training course for non-CTIMP/MDCI research is updated every two years.

3.12 For both sponsored and hosted studies, staff working on the study must be named on a Delegation Log where appropriate (see TMP-QA-13). Documented evidence of GRP training, commensurate with the role they have in the study, must be available.

3.13 If a research activity is part of a person's normal clinical role and all other protocol activities are undertaken by a member of the research team, then no GRP training may be required, however this should be confirmed with the Sponsor.

Sponsorship

3.14 For research sponsored or co-sponsored by NHSG and/or UoA, evidence of valid GRP training for the CI and any local co-investigators is highly recommended (and may be stipulated by Sponsor on a risk adapted basis). If no valid evidence is available, the CI shall be directed to the Training Team who shall offer appropriate training courses.

R&D permission

3.15 For research locally sponsored or hosted by NHSG, evidence of valid GRP training for the PI is **highly recommended** and shall be checked upon receipt of application for R&D permission. If no valid evidence is available, the PI shall be directed to the Training Team who shall offer appropriate training.

Training records

3.16 Certificates of evidence of GCP/GRP training for **all** researchers shall be kept in the TMF/ISF and within staffs' individual training records (see SOP-QA-2 - Training record). In addition, it is recommended that the Curriculum Vitae of researchers includes the date of attendance at a GCP/GRP course.

4. Abbreviations and definitions

CI	Chief Investigator
CSOG	Clinical Studies Oversight Group
CTIMP	Clinical Trial of Investigational Medicinal Product
GCP	Good Clinical Practice (ICH GCP – International Conference on Harmonisation)
GRP	Good Research Practice
ISF	Investigator Site File
MDCI	Medical Device Clinical Investigation
PI	Principal Investigator
SIV	Site Initiation Visit
TMF	Trial Master File

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5. Related documentation and references

NHSG-RD-Doc-023	GCP Training letter
SOP-QA-2	Training Record
TMP-QA-13	Site Delegation Log
TMP-QA-22	Employee Training Record CV

References

1. UK Policy Framework for Health & Social Care Research (2017)
2. SI 1031 Statutory Instrument 1031 (Medicines for Human Use (Clinical Trials) Regulations) 2004
3. SOP-QA-3 Protocol guidance for use in high risk trials and CTIMPs
4. SOP-QA-4 Applying for sponsorship
5. ICH GCP Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)

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