

Glasgow Clinical Trials Unit Guideline

Guideline Number	57.015B	Version	1.0
Title	NRS GCP Course		

GCRF is the national lead for NHS Research Scotland Good Clinical Practice courses. This guidance document describes the process when reviewing an NHS Research Scotland Good Clinical Practice course.

Procedure

1. NRS Introduction to GCP Course Review – minimum of 6 month process

The reviewer:

- Contact MHRA GCP Inspector to confirm available to collaborate and a date to meet virtually to discuss and review initial changes.
- Research current regulations, guidance, frameworks, policies and resources to up-date course content as required.
- Send first draft to MHRA GCP Inspector.
- Update changes to PowerPoint and documents following discussion.
- Final agreement with MHRA GCP Inspector of course content and materials.
- Arrange a 'Train the Trainer' date and time with NRS GCP Trainers.
- Finalise all documents.
- Complete the train the trainer event.
- Inform E&Q Administrator when review completed, confirming date new version can be used.

The E&Q Administrator:

- Upload new version of documents to shared portal.
- Inform NRS Trainers documents are available to access and use.
- File documents in master folder in common drive and retain superseded version for 5 years.
- Maintain record of all delegates that register and attend the course.

2. NRS GCP Update Course Review

The NRS GCP Update course must be reviewed every 2 years, this is a 9 month process.

The reviewer:

- Start initial research on changes to regulations, standards and guidance, considering hot topics identified on MHRA website, MHRA blogs, HRA (as examples).
- At NRS Trainers Forum meeting set out key/hot topics for new update course content and invite suggestions.
- Contact MHRA GCP Inspector to confirm available to collaborate and a date to meet virtually for initial discussion.
- Send first draft to MHRA GCP Inspector.

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- Amend content as required
- Pilot first stage of new version within E&Q team.
- Amend course content and materials to reflect feedback.
- Send updated final version to MHRA GCP Inspector for review
- Update any changes as requested.
- Pilot new version in GGC to small group of selected staff (external to E&Q team).
- Finalise all documents and update version number.
- Arrange a Train the Trainer date for NRS Trainers.
- Inform E&Q Administrator when review completed, confirming date new version can be used.

The E&Q Administrator:

- Upload new version of documents in shared portal.
- Inform NRS Trainers documents are available to access and use.
- File documents in master folder and retain superseded version for minimum of 5 years.
- Maintain record of all delegates that register and attend the course.

NRS Lead:

- Arrange QA date with GCP instructors within next 3-12 months of train the trainer event and documents being made available for all NRS GCP Update Trainers.

3. Delivering a course

The GCP trainer:

- Confirm date, time, online/face-to-face, if appropriate venue and access time to venue.
- Access, check version number, and download if required, materials required to deliver the course. GCP materials accessed via shared portal.
- Trainer to co-ordinate collection of printed materials when necessary (e.g. spare delegate pack/course materials)
- Completed registration list.

The E&Q Administrator:

- Prepare and distribute necessary materials prior to date:
- Online: email link to join the course and delegate pack to registered attendees, copying in education team.
- Face-to-face: email reminder and directions to registered attendees. Email or print delegate packs as appropriate for individual courses, prepare certificates.
- Email certificate to delegates.
- Update GCRF Course spreadsheet with attendance details.

Guideline signatories

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Document history

Version	Date	Description	Retrospective Implementation
1.0	27/11/2025	Creation of guidance document	No

This Guideline is a controlled document. The current version can be viewed on the R&I website, GCTU website and R&I's Q-Pulse account.

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