

MANDATORY

GUI 57.010E: Localising Participant Facing Documents

The following guidance is to ensure quality and consistency when adding local information to participant facing study documentation. This guidance should be applied to documents that have Research Ethics and Local R&D Permission.

Procedure

1. The following participant documentation must be presented on NHS Greater Glasgow & Clyde (GG&C) headed paper:
 - Participant Information Sheet (PIS)
 - Consent Form
 - GP Letter
 - Other documentation, at Sponsor request
2. A copy of NHS GG&C logo can be found saved in *GCRF Forms and Templates* shared folder.
3. Full address of specific GCRF site must be recorded on PIS and GP Letter.
4. Consent Form may be attached to PIS, NHS GG&C logo must be recorded on both documents.
5. Contact details for both Principal Investigator and Research Study Nurse may be recorded on PIS.
6. PIS may request independent contact for advice and complaints, details of Patient Advice and Support Service (PASS) can be found in NHS GG&C Complaints Policy.
7. NHS GG&C logo and PI contact details must be recorded on participant GP letter.
8. Changes to the content to the documents must not be made. If there are queries regarding the content should be directed to sponsor.

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1.0	21/05/2018	Creation of Guidance document