**Research Study Site File Index
& supporting documents**

NHS Greater Glasgow & Clyde (NHS GG&C) requires all researchers to have a study file for every research project requiring ethical and Board approval.

Enclosed is a site file index which will assist in formatting a study file and identifies the documents that are required. This index may also be used for non NHS GG&C sponsored studies if an index has not been supplied by the sponsor and the study team has obtained the sponsors approval. All studies conducted within NHS GG&C may be subject to research audit.

If you require information on any sections of the site file index, please discuss with the R&D Coordinator or contact the R&D Research Audit Facilitator: eileen.mccafferty2@ggc.scot.nhs.uk

All study documents should be version controlled and previous versions scored through and marked “superseded”.

If a section is not relevant to your study, indicate N/A.

Enclosed within this pack are the following supporting documents which should be used, as appropriate, for your study:

* Key contacts details
* Responsibilities log
* Site Tracker/Protocol/Amendment distribution log (multi site studies)
* Patient identification log
* Patient screening/recruitment/withdrawals log
* Training log
* File note template
* Archiving log

For information and advice on version control, good documentation practice, and safety reporting, discuss with your R&D Coordinator and refer to the relevant Standard Operating Procedures on the Glasgow Clinical Trials Unit website: <http://www.glasgowctu.org/sops.aspx>, e.g.

* Case Report Form (CRF) Completion
* Good Documentation Practices
* Safety Reporting Requirements for Research Other Than Clinical Trials of Investigational Medicinal Products

Training is available from NHS GG&C for research purposes. For a complete list and dates, please contact <http://www.glasgowcrf.org.uk/courses.htm>

**Site File Index**

**1. Contact Information**

1.1 Sponsor

1.2 Chief Investigator

1.3 Key contact(s) detail(s)

1.4 Principal Investigator(s) at participating site(s) (if appropriate)

1.5 24 hour contact number (for study participants and study site personnel)

**2. Study Correspondence**

2.1 General correspondence: letters, faxes, emails files, significant phone calls in date order with most recent at top

2.2 Site file guidance notes

**3. Protocol and related documents**

3.1 Current, signed version of protocol, numbered and dated

3.2 Superseded protocols

3.3 Site Tracker/Protocol/Amendment distribution log (multi-site studies only)

3.4 Patient Information Sheet: all versions

3.5 Informed Consent Form: all versions

3.6 Patient diaries (if applicable): all versions

3.7 Questionnaires (if applicable): all versions

3.8 GP letter: all versions

3.9 Posters/advertisements: all versions

**4. Ethics**

4.1 Original NRES form or IRAS application for REC

4.2 Favourable opinion letter(s): REC

4.3 Ethics correspondence

4.4 Annual progress report(s)

4.5 Final report to Ethics

**5. Funder**

5.1 Grant application

5.2 Award letter

5.3 Evidence of peer review (non eligible study)

5.4 Progress report/final report

5.5 Related correspondence, filed in date order with most recent at top

**6. NHS GG&C Board Approval documents**

6.1 IRAS Research and Development form plus Site Specific Information

6.2 Board approval: main site and additional sites (if applicable)

6.3 Agreements/contracts

6.4 Honorary contract/letter of access

6.5 ARSAC certificate (if appropriate)

6.6 Study teams CVs: signed and dated

6.7 Publication/abstract

**7. Sponsor**

7.1 Related correspondence, filed in date order with most recent at top

7.2 UKCRN spreadsheet

**8. Safety information/reporting**

8.1 AE/SAE reporting forms

8.2 Copies of all AEs/SAEs

**N.B. For research studies classified as high risk, SAEs should be faxed to 0141 357 5588**

8.3 Related safety correspondence

**9. Study documents**

9.1 Sample CRF/data collection form/questionnaire – version controlled

**NB: Completed CRFs/data collection forms must be stored securely and separately from all other study documentation**

9.2 Responsibilities log: signed and dated by study team

**10. Good Clinical Practice for research studies**

10.1 Audit report(s)

10.2 Training logs

10.3 Study specific Standard Operating Procedures/Work Instructions

**11. Amendments**

11.1 Notification of amendment form(s)

11.2 Amendment(s) favourable opinion letter

11.3 Board approval of amendment(s)

**12. Screening and recruitment**

12.1 Patient screening/recruitment/withdrawals record

12.2 Patient identification log

12.3 Recruitment status

12.4 Original signed and dated versions of informed consent forms

**13. Body fluid/tissue sample retention**

13.1 Record of retained body fluids/tissue samples

13.2 Bio-repository paperwork

**14. Investigator meetings**

14.1 Minutes of Investigator meetings

**15. Laboratory / Equipment**

15.1 Calibration logs/other

15 2 Temperature logs

15.3 Reference ranges

15.4 Accreditation certificates

**16. Archiving**

16.1 Archiving log

**17. File notes**

17.1 Completed, signed and dated file note(s)

**18. Other**