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| Form number | **Form 56.001H** | Version  | **1.0** |
| Title | **Principal Investigator Site File Index (non-CTIMP): Template** |

**Principal Investigator Site File Index (non-CTIMP):**

**Essential clinical trial documentation for Academic (Non-Commercial) Trials**

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

This template has been produced by NHS GGC Research and Innovation to assist the **Principal Investigator** / study team in formatting their study site file. However, as this is merely a template which sites may make use of, it is acceptable also for sites to make use of any local indexes available unless otherwise stated.

The purpose of a site file is to contain the essential documents which reflect the conduct of the trial and is therefore a key element in trial reconstruction.

The site file must be established at the beginning of the trial, be rigorously maintained on an ongoing basis and available at any time for monitoring, audit or inspection purposes. An incomplete or not up to date site file may result in findings from monitoring visits or audits and is regarded as the source of truth, documents must be located in the site file to be regarded as being in place.

All academic trials within NHS GG&C will potentially be subject to good clinical practice (GCP) audit, in conjunction with routine monitoring.

It should be noted that the documentation in the site file will vary slightly, depending on the study type. The template index should be amended to reflect local activity.

The **Principal Investigator** is responsible for the documentation and conduct of the trial at the participating site and transfer of information to the main site.

**Investigator Site File Index**

**Section 1: Contact information**

1. Sponsor details
2. Chief Investigator details
3. Site contact details
4. In-hours site contact number for study participants
5. 24 hour site/ emergency contact number for study participants/ Out-of-hours contacts for participants (if applicable)

**Section 2: Study correspondence**

1. General correspondence: letters, newsletters, emails filed in date order with most recent at the top

**Section 3: Protocol and amendment(s)**

* + 1. Current version of protocol
		2. Protocol signature page
		3. Superseded protocol(s)
		4. Amendments, numbered (summaries of changes)
		5. Protocol Deviation Form
		6. Protocol Deviation Log
		7. Completed Protocol Deviation forms

**Section 4: Ethics**

1. Favourable opinion letter(s) (including Ethics Committee members)
2. Amendment(s) favourable opinion letters
3. Correspondence: letters, faxes, emails filed in date order with most recent at top
4. End of trial notification

**Section 5: R&I/Sponsor**

1. Management approval (local)
2. Management approval following substantial amendment(s)
3. Localised OID
4. Site agreement / mNCA (or filenote to signpost location)
5. Correspondence: letters, emails filed in date order with most recent at top

**Section 6: Critical maintenance documents**

1. PI CV/GCP certificate
2. Study team CVs
3. Site Delegation Log
4. Screening Log
5. Participant Enrolment Log
6. Other study specific logs as instructed

**Section 7: Trial documentation**

1. Current version of Participant Information Sheet (and superseded versions)
2. Current version of Informed Consent Form (and superseded versions)
3. Patient approach / invitation templates (and superseded versions), if applicable
4. Study/participant alert card, if applicable
5. GP letter(s) (and superseded versions), if applicable

**Section 8: Pharmacovigilance**

1. SAE reporting forms (including Pregnancy Notification forms)
2. Completed SAE / Pregnancy reports
3. Reference Safety Information (if applicable)
4. Correspondence: letters, emails filed in date order with most recent at top

**Section 9: Case Report Form**

1. Sample CRF (if applicable)
2. CRF completion guidelines
3. Data queries and correction forms
4. Electronic data capture information (user manual, training log)

**Section** **10: Sample Handling / Laboratory / Medical devices**

1. Medical devices: records of maintenance and testing (if applicable)
2. Sample Handling manual (if applicable)
3. Laboratory Sample Forms (if applicable)
4. Laboratory certificates – accreditations
5. Laboratory reference ranges

**Section 11: GCP**

1. GCP guidelines
2. Monitoring documentation (visit log, agenda follow up letter, actions resolution documents), if applicable
3. Training information (e.g. SIV or Investigator Meeting slides)
4. Clinical trial training records (as appropriate including documentation of amendment training)
5. Policy for GCP training for personnel involved in clinical research
6. File note template

**Section 12: Study Specific Manuals / instructions**

1. As agreed

**Section 13: Patient Sourced Data**

1. Completed Source Data Plan (if applicable)
2. Signed participant consent forms (original)
3. Completed CRFs (if applicable)
4. Participant diaries, questionnaires (as applicable)

**Section 14: Completed File Notes**