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| Form number | **Form 51.016C** | Version | **3.0** |
| Title | **Principal Investigator Site File:Template** | | |

**Principal Investigator Site File:**

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

The Trial Master File (TMF) is a legal requirement for clinical trials that come under the Medicines for Human Use (Clinical Trials) Regulations 2004 as amendedand major non compliances can now lead to prosecution. NHS GG&C divides the TMF into two separate categories:

* Sponsor File (Maintained by Sponsor)
* Investigator Site File (Maintained by Sites)

Each category abides to a separate index which collectively represents the TMF.

This template has been produced by NHSGGC 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. Additionally, academic clinical trials under the scope of the Regulations will, potentially, be subject to regulatory inspection from the Medicines and Healthcare products Regulatory Agency (MHRA).

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 contacts 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 (as applicable)
6. Emergency unblinding details (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: Regulatory (MHRA)**

1. Regulatory approval letter
2. Amendment Acceptance letters
3. Correspondence: letters, emails filed in date order with most recent at top
4. End of trial Declaration

**Section 7: Critical maintenance documents**

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

**Section 8: Trial documentation**

1. Current version of Patient Participant Information Sheet (and superseded versions)
2. Current version of Informed Consent Form (and superseded versions)
3. Patient approach / invitation templates (and superseded versions)
4. Study/participant alert card
5. GP letter(s) (and superseded versions)
6. Labels (e.g. case note)

**Section 9: Pharmacovigilance**

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

**Section 10: Case Report Form**

1. Sample CRF (if applicable)
2. Completed CRF’s (if applicable)
3. CRF completion guidelines
4. Data queries and correction forms
5. Electronic data capture information (user manual, training log)
6. Source data plan (if applicable)

**Section** **11: Sample Handling / Laboratory / Medical devices**

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

**Section 12: GCP**

1. GCP guidelines
2. Monitoring documentation (visit log, agenda follow up letter, actions resolution documents)
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

**Section13: Investigational Medicinal Product (IMP)Information**

1. IMP clinical information and updates (Investigator Brochure/SmPC as applicable)
2. IMP Management & Accountability Manual for Sites
3. Clinical trial prescription form(s)
4. IMP administration records (if applicable)
5. Documents related to storage of IMP out-of-pharmacy (if applicable)
6. Information on Non-investigational Medicinal Products (NIMPs)

**Section 14: Study Specific Manuals / instructions**

1. As agreed

**Section 15: Patient Sourced Data**

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

**Section 16: Completed File Notes**