

SOP-QA-8 V4

Title: Investigator Site File (ISF)

Effective Date: 9-8-23

Review Date: 9-8-26

Author: Louise King, Research Governance Manager

QA Approval: Richard Cowie, QA Manager

Approver: Prof Maggie Cruickshank, R&D Director

Approver: Prof Siladitya Bhattacharya, Head of School



GRAMPIAN CLINICAL RESEARCH OFFICE



Document History

Version	Description of update	Date Effective
3	Change to scope at 1.2 and 1.5 removed. Abbreviations added at 4	1-8-20
4	Minor updates throughout SOP Clarification on SOP relevance and update scope at 1 Reference to Electronic ISF to be held securely at 3.2	9-8-23

1. Scope

- 1.1 This SOP applies to all researchers, Sponsor staff, Clinical Trial Pharmacy staff and laboratory staff involved in projects sponsored, or co-sponsored, by the University of Aberdeen (UoA) and/or NHS Grampian (NHSG). This procedure does not apply to commercially sponsored research or research sponsored by an external non-commercial organisation (in such cases the external Sponsor shall provide guidance).
- 1.2 **⚠** For Clinical Trials of Investigational Medicinal Products (CTIMPs) and Medical Device Clinical Investigations (MDCIs), a Trial Master File (TMF), which contains all the essential documents relating to the clinical trial, must be established and maintained. The requirement is set down in both EU and UK legislation (2001/20/EC Article 15(5) and SI 2004/1031 [as amended] 31A).
- 1.3 The TMF forms the basis for an inspection to confirm compliance with regulatory requirements (Directive 2005/28/EC Chapter 4, Article 16). In most studies there will be investigator site files (ISF) and these form part of the TMF (SOP-QA-7).

2. Responsibilities

Principal Investigator (PI) Setting up/control of the Investigator Site File (may be delegated).

3. Procedure

Establishing an Investigator Site File


- 3.1 **!** The ISF shall be established at the beginning of the trial, prior to patient recruitment.
- 3.2 **!** The PI shall keep the ISF in a lockable cabinet or room, with restricted access. If the ISF (or aspects of the ISF) are held electronically, these should be held on a secure network drive.
- 3.3 The ISF shall be set up using an ISF Index (TMP-QA-50; non-CTIMP). For CTIMPs or MDCIs, the ISF should be adapted appropriately.

Uncontrolled when printed. Please ensure that you are working on the most up to date version of this SOP

Key to symbols **!** = Important point to note **⚠** = Warning

- 3.4 If a document is not considered applicable then this should be documented in the ISF index. Some ISFs may be totally, or partly electronic in format, and for these, the exact locations of documents shall be clearly stated on the ISF index, which itself may be filed electronically. For hard copy ISFs, the ISF index must be kept in the front of all files.

Maintaining an Investigator Site File

- 3.5 The PI is responsible for updating the ISF with any relevant and applicable documentation as the trial progresses, in accordance with the ISF index. If a document is not located in the ISF, a note to file shall be completed to detail the location and/or reason for this. The ISF need only contain documents specific to the local site.
- 3.6  All filing must be done in a timely manner. Documents must be filed chronologically.
- 3.7 Correspondence which is necessary to construct key activities and decisions must be retained. Key email correspondence must be saved and filed individually and not as conversations.
- 3.8 Version control must be applied to all trial documents and shall use whole numbers only (see SOP-QA-1 - Management of SOPs). Outdated documents must be retained and identified as superseded. New versions of the protocol shall be signed and dated prior to use.
- 3.9 The ISF must be made available to Trial Monitors and representatives of the Medicines and Healthcare products Regulatory Agency (MHRA), upon request.

Archiving an Investigator Site File

- 3.10 Once the trial has finished, the PI is responsible for reviewing the ISF to ensure that all the required documents are present. The site agreement will determine whether the ISF is archived on site or at the Sponsor's chosen archive facilities (see SOP-QA-32 – Archiving).


4. Abbreviations and definitions

CTIMP	Clinical Trial of an Investigational Medicinal Product
MDCI	Medical Device Clinical Investigation
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
TMF	Trial Master File
ISF	Investigator Site File

5. Related documentation and references

SOP-QA-1	Management of SOPs
SOP-QA-7	Trial Master File
SOP-QA-27	Good documentation practice
SOP-QA-31	Research project closure
SOP-QA-32	Archiving
TMP-QA-13	Site delegation log
TMP-QA-50	ISF Index (non-CTIMP)

Uncontrolled when printed. Please ensure that you are working on the most up to date version of this SOP

Key to symbols  = Important point to note  = Warning