

## SOP-QA-6 V5

**Title: Study start-up**

Effective Date: 21-6-24 | Review Date: 21-6-27

Author: Louise King, Research Governance Manager

QA Approval: Richard Cowie, QA Manager

Approver: Prof Seshadri Vasam, R&D Director

Approver: Prof Siladitya Bhattacharya, Head of School




GRAMPIAN CLINICAL RESEARCH OFFICE



### Document History

| Version | Description of update   | Date Effective |
|---------|---|----------------|
| 4       | RGM changed to RGT at 2<br>Site delegation log changed to study delegation log at 3.1 and 3.7<br>Minor changes to text at 3.2 and 3.6, HRA added at 3.5<br>'Other study start-up activities' revisions at 3.11-3.17 | 21-6-21        |
| 5       | Minor changes to text for clarity – 3.1,3.2,3.6 and 3.12  | 21-6-24        |

### 1. Scope

- 1.1 This SOP applies to all research and Sponsor staff participating in, or supporting, research projects sponsored or co-sponsored by University of Aberdeen (UoA) and/or NHS Grampian (NHSG).
- 1.2  As part of the set-up process and to comply with the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004 No 1031) as amended, the principles of Good Clinical Practice (GCP), Clinical Trials of Investigational Medicinal Products (CTIMPS) and Medical Device Clinical Investigations (MDCI) must have a Trial Master File (TMF).

### 2. Responsibilities


|                                |  |
|--------------------------------|--|
| Sponsor                        | Setting up a trial (usually delegated to Chief Investigator) |
| Chief Investigator (CI)        | Setting up a trial (usually delegated to the CI by Sponsor)  |
| Research Governance Team (RGT) | Risk assessment of study                                     |
| Research Monitor               | Perform site initiation monitoring visit                     |

### 3. Procedure



- 3.1 For clinical research projects sponsored or co-sponsored by UoA and/or NHSG, the responsibility for setting up a project will be delegated to the Chief Investigator (CI) by the Sponsor. For CTIMP/ MDCI projects this delegation of responsibility shall be agreed **before** the trial commences and shall be documented in the sponsorship and/or site agreements. The CI may delegate the responsibility for performing some project set up activities to members of the research team; this delegation of responsibility must be formally documented in the **Site delegation log** (TMP-QA-13) or co-sponsorship agreement where delegated to a CTU.
- 3.2 All CTIMP and MDCI trials shall be subject to a study initiation from a Research Monitor (see SOP-QA-28 – Monitoring). Other study types may also be subject to a study initiation but this will be determined by the Sponsor based on risk.

**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

- 3.3 Trial set up procedures eg establishing a TMF, SOP training for trial team, site initiation visit and establishing a project management/oversight committee, may be performed before or after all appropriate approvals are in place, but must be in place **before** the first subject is recruited.
- 3.4  The Sponsor and investigator shall maintain a record of the location of respective essential documents (including electronic data). This may utilise the existing file indexes (see 5).




### Approvals

- 3.5  It is the responsibility of the CI to ensure sponsorship, a favourable ethics opinion, MHRA approval (if required), HRA approval (if required) and NHS R&D Management Permission are in place before recruitment begins.
- 3.6  For multicentre studies, it is the responsibility of the CI and/or PI(s) to ensure that site specific NHS R&D Management Approval/ Capacity and Capability (C&C) has been obtained and that the appropriate contracts and site initiation procedures are in place **before** recruitment can commence at each of the trial sites.

### Establishing a Trial Master File (TMF) including Investigator TMF





- 3.7  The CI is responsible for ensuring a TMF, with all required documents, is set up **prior** to recruitment commencing (see SOP-QA-7 - Trial Master File). This may be delegated to another member of the research team and documented in the study delegation log or equivalent.
- 3.8  Where Sponsor template forms are not used for safety reporting eg SAE forms (TMP-QA-10), pregnancy notification (TMP-QA-12) the study specific forms must be reviewed and approved by Sponsor **prior** to recruitment commencing.
- 3.9  The TMF shall be kept securely and updated with documents as the trial progresses.
- 3.10  Multi-centre studies require an Investigator Site File (ISF) at each site **before** recruitment begins. The lead site may combine this with the TMF (see SOP-QA-8 - Investigator Site File).

### Other study start-up activities

- 3.11  **Before** recruitment can begin the CI shall develop procedures and systems to ensure that they conduct the study in accordance with the appropriate regulations. Some examples include:
- Establishing oversight committees (see SOP-QA-17- Project committees).
  - Archiving arrangements **including responsibility for costs** (see SOP-QA-32 – Archiving).
  - Ensuring that all trial supplies, resources, and facilities, have been ordered and are available before recruitment commences eg IMP, case report forms, Imaging etc (see SOP-QA-16 – Selection and Management of Third Parties, and SOP-QA-38 -Equipment).
  - Ensuring data capture/management systems are in place (see SOP-QA-20 – Data Management).
  - The study is registered on a suitable publicly available platform prior to recruitment.
  - Ensuring appropriate training (protocol and SOPs) for members of the study team (see SOP-QA-2 -Training record).
- 3.12  For CTIMPs, the CI (and PIs in a multi-centre study) shall ensure that appropriate IMP storage and accountability has been discussed and agreed with the relevant Clinical Trial Pharmacy(s).
- 3.13  For MDCIs, the CI (and PI in a multi-centre study) shall ensure that appropriate device storage and accountability has been discussed and agreed with Sponsor and the Manufacturer.

**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

- 3.14  The delegation log shall document the members of the research team and the trial duties they are authorised by the CI to conduct. Each member of the research team shall sign the study delegation log and be able to demonstrate that they are qualified by training and experience to perform their delegated tasks (see SOP-QA-2 - Training record).
- 3.15  For CTIMPs and MDCIs, The Regulatory Green Light form shall be completed and signed by the Research Governance Manager and Clinical Trial Pharmacist (CTIMP only) **prior** to any recruitment taking place.
- 3.16  UoA/NHSG recommend that all CTIMP participants are issued with 'In case of emergency' cards to be carried at all times. Minimum details on the card shall include the trial emergency contact number, CI name, study identifier, details of the IMP and the name of the participant. In studies where an emergency card is not required, this shall be agreed with Sponsor during protocol development.
- 3.17  In trials with an emergency phone number or unblinding system, consideration shall be given to testing the emergency phone number and/or the un-blinding system prior to recruitment of the first participant. This process shall be documented and filed in the TMF.

#### 4. Abbreviations and definitions

|       |   |
|-------|---|
| CI    | Chief Investigator                                  |
| CTIMP | Clinical Trial of Investigational Medicinal Product |
| DMC   | Data Management Committee                           |
| GCP   | Good Clinical Practice                              |
| HRA   | Health Research Authority                           |
| IMP   | Investigational Medicinal Product                   |
| ISF   | Investigator Site File                              |
| MDCI  | Medical Device Clinical Investigation               |
| MHRA  | Medicines and Healthcare products Regulatory Agency |
| PI    | Principal Investigator                              |
| RGT   | Research Governance Team                            |
| TMF   | Trial Master File                                   |
| TMG   | Trial Management Group                              |
| TSC   | Trial Steering Committee                            |

#### 5. Related documentation and references

|           |   |
|-----------|---|
| SOP-QA-2  | Training record                               |
| SOP-QA-7  | Trial Master File                             |
| SOP-QA-8  | Investigator Site File                        |
| SOP-QA-16 | Selection and Management of Third Parties     |
| SOP-QA-17 | Project committees                            |
| SOP-QA-20 | Data Management)                              |
| SOP-QA-28 | Monitoring                                    |
| SOP-QA-32 | Archiving                                     |
| SOP-QA-38 | Equipment and Facilities                      |
| TMP-QA-3  | Trial Master File Index (CTIMP and High Risk) |
| TMP-QA-10 | SAE reporting Form                            |
| TMP-QA-12 | Pregnancy Notification Form                   |
| TMP-QA-32 | Sponsor File Index                            |
| 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