SOP-QA-6 V4

Title: **Study start-up**	
Effective Date: 21-6-21	**Review Date: 21-6-24**
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Document History

Version	Description of update	Date Effective
1	Change of number for Q-Pulse	2-10-15
2	Reformatted Requirement to maintain a record of the location of essential documents	1-4-17
3	Reference to Green Light process at 3.15	1-6-18
4	RGM changed to RGT at 2 Site delegation log changed to study delegation log at 3.1 and 3.7 Minor changes to text at 3.2 and 3.6, HRA added at 3.5 'Other study start-up activities' revisions at 3.11-3.17	21-6-21

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 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 trial will normally be delegated to the Chief Investigator (CI) by the Sponsor. 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 trial 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).

3.2 All studies assessed by the Sponsor risk assessment process as higher risk, shall be subject to a study initiation from a Research Monitor (see SOP-QA-28 – Monitoring).

3.3 Trial set up procedures eg establishing a Trial Master File (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 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 responsibility 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. At the lead site this may be combined 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 (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 PI in a multi-centre study) shall ensure that appropriate IMP storage and accountability has been discussed and agreed with the Clinical Trial Pharmacy (CTP).

3.13 ⚠ For Medical Device Clinical Investigations (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.

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)