SOP-QA-40 V4

Title: Multi-centred site selection

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Document History

Version	Description of update	Date Effective
3	Reference to sub-studies at 1.2 and minor change to text at 1.2 and 3.4 Potential participants changed to potential recruitment target at 3.3	21-6-21
4	Scheduled review at three years. No updates required.	21-6-24

1. Scope

1.1 This SOP applies to any individual, or Clinical Trial Unit (CTU), undertaking multi-centred research sponsored, or co-sponsored, by University of Aberdeen (UoA) and/or NHS Grampian (NHSG). It also applies to the Sponsor themselves; who must provide oversight of site selection.

1.2 The selection of suitable sites and investigators is crucial to the delivery of multi-centred research projects. It is ultimately the Sponsor's responsibility to approve investigators and institutions to participate in research it sponsors. Sponsor shall oversee, and the Chief Investigator (CI) and other members of the trial team shall evaluate and select sites and investigators for multi-centred projects. This includes investigators, institutions and/or sites for any sub-studies which may be undertaken.

1.3 The Sponsor, through the CI or delegate, shall ensure that each investigator is qualified by skills, training (including recognised Good Clinical Practice (GCP) training, where appropriate) and relevant experience, and that both the investigator and site have adequate resources to conduct the research in compliance with the protocol and principles of GCP **before** any research procedures commence.

2. Responsibilities

Sponsor	Overview of evaluation and selection of sites and investigators.
Chief Investigator	Identify suitable sites and investigators in liaison with Sponsor.

3. Procedure

3.1 Initial identification of potential collaborating investigators/sites may be on the recommendation of the CI, based on professional and/or personal experience of working with the potential investigator /site. An existing Principal Investigator (PI) or the Sponsor, may also identify potential collaborating investigators/sites. A recommendation may also be received through the Clinical Research Network or a Clinical Research Organisation.

3.2 Once a potential collaborating investigator/site has been identified, an evaluation against specific criteria shall be conducted by the CI or delegate.

3.3 Evaluation criteria may include (but is not limited to) responses to the following and shall be documented, along with any associated correspondence, in the Trial Master File (TMF):

- Previous involvement of the PI and/or site in research.
- Interest and commitment of the PI in collaborating with the research project.
- Does the PI and/or site have any competing trials open or in set up?
- Qualifications of the PI (eg current CV, GCP training and details of recent and current studies, projects and publications).
- Qualifications, training and experience of clinical staff (eg other clinicians, nurses and relevant healthcare professionals).
- Availability of any specialist equipment or facilities (eg imaging, Containment Level 3 or Genetically Modified Organism approved facilities).
- Laboratories (eg Quality Management System, accreditation, certification*, resources).
- Pharmacy (eg Quality Management System, specialist Clinical Trial Pharmacy staff, resources).
- IT (eg compatible systems, equipment availability, IT security).
- Storage (eg temperature control of samples or reagents and archive facilities (if required)).
- Security (eg lockable rooms or filing cabinets for trial data).
- Access (eg for research team training or monitoring).
- Potential recruitment target.
- Communication (eg Potential language barrier).

Consideration shall also be given to any budget consideration (eg start-up costs, per patient fees and funds for equipment, consumables and any associated archiving costs) and additional resources from research staff (including CTU) in supporting/servicing an additional investigator/site.

*Laboratories should be suitably accredited (ie GLP, ISO 15189:2022 or ISO 17025:2017) or certificatied (ie ISO 9001:2015) and the tests being performed should be on their scope of testing.

3.4 Based on the evaluation, the CI shall decide on the suitability of the potential investigator/site and submit to Sponsor for approval. If the Sponsor agrees the potential investigator/site shall be progressed. The decision outcome shall be documented in the TMF and appropriate site agreement (see SOP-QA-13 – Generation of contracts).

3.5 It may be appropriate for the Sponsor to visit a potential collaborator or site. Any site selection visit shall be documented appropriately (eg as an audit report) and filed in the TMF.

3.6 No recruitment activities shall be undertaken by a potential collaborator or site until all appropriate approval, contracts and documents are in place (including completed delegation log, research team CVs, current GCP certification and any green light process).

4. Abbreviations and definitions

CI	Chief Investigator
CTU	Clinical Trial Unit
GCP	Good Clinical Practice
PI	Principal Investigator
TMF	Trial Master File

5. Related documentation and references

SOP-QA-13	Generation of contracts.