STANDARD OPERATING PROCEDURE FOR SELECTING SITES & INVESTIGATORS

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1. PURPOSE

This document describes the procedure used for selection of collaborating sites and investigators. Successful selection of collaborating sites and investigators is crucial to the delivery of a study and the quality of the data collected and is a key component in meeting the requirements of GCP and the UK Policy Framework for Health and Social Care Research.

Sites and investigators may be identified during the funding application stage based on established collaborations. However, additional sites and investigators may require to be confirmed prior to study start or as the study progresses.

Care should be taken when identifying sites and investigators to ensure that there are sufficient resources (staff, equipment etc.), facilities (laboratories) and potential participants

The aim of this SOP is to provide a structured mechanism to standardise the selection of sites and investigators.

It is the responsibility of all researchers using this SOP to ensure they are using the latest version of it. The latest version is available via the R&D pages on the NHS Fife Intranet (www.nhsfife.org/research). For guidance, contact the R&D Department via fife-uhb.randd@nhs.net

2. APPLICABILITY

This SOP applies to a Chief Investigator (CI) or other members of staff who are responsible for selecting sites and/or investigators for clinical research studies sponsored or co-sponsored by NHS Fife. This SOP is intended for use as a procedure for the selection of sites or Principal Investigators (PI) and documents the process by which the CI and/or other members of the study team evaluate and select a site or investigator for participation in a clinical research study.

3. POLICY

Selection of the correct sites and investigators is crucial to the successful delivery of a clinical study. The quality of the data collected and the speed of collection depends primarily on who is responsible for participant identification and recruitment, study management, data collection and the way these activities are managed. Poor selection can lead to low quality data, slow recruitment and high levels of data queries.

In accordance with ICH GCP Guidelines and the UK Policy Framework for Health and Social Care Research, it is ultimately the Sponsor's responsibility to select the investigator(s) and institutions. The Sponsor together with the CI and study team should ensure that each

investigator is qualified by skills, training (including GCP) & experience and that sites and investigators have adequate resources to properly conduct the study.

In order to evaluate sites and investigators, the CI and other trial personnel will assess them against study specific criteria to ensure suitability, before the PI or site is formally engaged as a site.

4. PROCEDURE

4.1 Identification of Sites

Initial identification of collaborating sites should be by recommendation of the CI, based on their professional and personal experience of working with a potential collaborator. Existing study PIs and NHS Fife staff can also recommend new sites and investigators. UK Sites can also be identified through the clinical research networks (CRNs) and NHS Research Scotland (NRS).

4.2 Evaluation

4.2.1 A study specific questionnaire should be completed to record and assess different criteria against which the site and potential PI will be evaluated. An example of this is given in the associated document "Site and Investigator Selection Evaluation Form" (Doc Ref 34-01).

4.2.2 A completed copy of the study specific questionnaire and associated correspondence will be filed in the Trial Master File.

4.3 Evaluation Criteria

The following list details the minimum criteria against which the site or potential PI should be evaluated:

4.3.1 *Interest of the PI* - the initial interest of the investigator is a good indicator of their commitment to the study. This can be as simple as a Yes or No response to the initial contact.

4.3.2 *Qualification of PI* - request current CV including details of recent and current studies and/or academic projects and publications.

4.3.3 *Experience of PI* – request details of recent and current studies and/or academic projects and publications.

4.3.4 *Local resources* – review qualifications, experience and capacity available of the following:

- Clinical staff required for the study (e.g. other clinicians, nurses, relevant healthcare professionals)
- Laboratories (e.g. what is needed and available locally, experience, SOPs, Quality Assurance)
- IT infrastructure and support (e.g. compatible systems, security issues, equipment available or needed)
- Storage and security (e.g. samples, documentation, temperature control considerations, lockable rooms, filing cabinets)

- Host infrastructure (e.g. who is the local signatory, how are finance and legal issues managed?)
- Transport links (e.g. how easy is it to visit the site for training and monitoring, how long will it take to travel there?)
- Availability of and accessibility to specialist equipment needed for the study (e.g. imaging)

4.3.5 *Suitable participant numbers* – request written evidence from the PI and/or site Research Nurse (recent/current) of recruitment to other studies, how many eligible participants does the investigators predict, how does the local participant population view clinical research, if available / known?

4.3.6 *Language barriers* – what measures are available for translation and back translation of trial documentation if required in protocol?

4.3.7 *Budget* – present start-up costs, per patient fee or project budget as appropriate detail of the funds available for equipment or consumables etc.

4.3.8 *Contacts* – Investigator(s), nurses, labs, finance, legal, R&D personnel etc.

4.4 Site visit

It may be desirable to visit the site prior to making the decision on selection of the site to ensure suitable facilities are available.

4.5 Evaluation outcome

4.5.1 Based on the response of the site representative and/or potential PI against the evaluation criteria, the CI and local study personnel will decide the suitability of the proposed investigator and/or site.

4.5.2 If the site and investigator are suitable, they will be invited by the CI or a representative of the study team to become a collaborating site.

4.5.2 If the site and/or investigator are not suitable, the site representative or investigator will be formally notified and thanked for their involvement to date. Where appropriate, feedback will be given to the site representative or investigator as to why they were not selected.

5. ASSOCIATED DOCUMENTS

Doc Ref 34-01 Site and Investigator Selection Evaluation Form

6. ABBREVIATIONS

CI	Chief Investigator
CRN	Clinical Research Network
GCP	Good Clinical Practice
NRS	NHS Research Scotland
PI	Principal Investigator
R&D	Research and Development
SOP	Standard Operating Procedure

7. REFERENCES

World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects.
(https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/)

Medicines for Human Use (Clinical Trials) Regulations 2004.
(http://www.legislation.gov.uk/uksi/2004/1031/contents/made)
It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.

8. DOCUMENT HISTORY

Version Number	Edited by (job title)	Effective Date	Details of Revisions Made
1	David Chinn Senior Research Advisor	30/03/2015	New - *Adapted from TASC SOP 51, version 1.0*
2	Julie Aitken R&D Trials Facilitator	06/12/2018	Reformatted in line with current SOP template. Revised to reflect current practice.

9. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research & Development Director, NHS Fife Signature: 	6th December 2018