STU-SOP-TS-006 – Standard Operating Procedure on Site Selection and Initiation

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure of site selection and initiation for any research project, taking into account research sponsor requirements.

2. Background

All STU SOPs are written in accordance with applicable Good Clinical Practice (GCP) requirements as outlined under the Research Governance Framework for Health and Social Care in Wales (RGF), and the UK clinical trials and devices regulations.

Research sponsors have a responsibility to select research investigators and research sites that are able to assume responsibility for the appropriate conduct of a research project.

All research investigators must have appropriate clinical and research experience, resources to carry out the research project and experienced staff to whom they can delegate research related duties. In addition, the site must be able to demonstrate the potential for recruiting and following up the required number of suitable participants within the agreed recruitment period.

All local approvals must be in place before the first participant is recruited.
This involves investigators and site staff being trained in the protocol, in use of any equipment to be used, any other research project specific procedures and data collection tools required. A Sponsor risk assessment process may establish when remote initiation can occur.

3. Roles and Responsibilities

The **Sponsor** is responsible for selecting appropriate Investigator(s) and Institution(s) for research projects. This role may be delegated to the Chief Investigator. Prior to initiating a research project, the Sponsor must complete agreements as appropriate for site.

Swansea Trials Unit (STU) are responsible for ensuring that Sponsor's responsibilities are met by coordinating the risk assessment process for adopted research projects where this task has been delegated. Further information can be found in STU-SOP-ADM-005 (Adoption) and STU-SOP-TS-005 (Risk Assessment).

The **Chief Investigator** (CI) is responsible for ensuring that site feasibility checks have been undertaken to assess a site's suitability for full delivery of the research project within the required time frame. The CI is also responsible for delivering training, conducting each site initiation or delegating this to a qualified member of the trial team.

The **Principal Investigator** (PI) at each site is responsible for providing the information requested during the site feasibility checks. The PI should be present at the site initiation meeting to confirm local practices and procedures.

The **Trial Manager** (TM) or delegate is responsible for ensuring that all tasks associated with the identification and initiation of each site are completed. The TM is also responsible for overseeing the completion of the delegation and training logs and issuing the initiation visit report.

External use of SOP: this SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

4.1 Site selection

Potential Investigator(s) and institution(s) are assessed by the Sponsor and CI. The Site Expression of Interest Form (STU-AD-FRM-016) can be used as a basis for this.

Investigators have a responsibility to demonstrate that their site can meet the recruitment target agreed with the Sponsor and CI.

The TM will compile the information and forward to the CI or Sponsor as required, with a recommendation of whether or not to proceed with the site based on information received and any relevant communications with site staff. The CI will make a final proposal for the Sponsor to consider.

Not all projects will require an extensive feasibility assessment of proposed sites, for example a single centre study that has been named in the funding application.

4.2 Site set up

A research project risk assessment (STU-SOP-TS-005) will usually have been completed and will help establish if a site can be initiated. Whilst an on-site visit is preferable, low risk projects may be allowed to conduct remote initiation using teleconferencing or videoconferencing facilities. In either instance the process will be described as a site initiation visit (SIV) and follow the procedures below.

Once the decision has been taken by the sponsor and CI to approve the research site, the TM will instigate the process of setting up site contracts and approvals.

Before the first site is set up, research project procedures e.g. training for the research team, establishing a Trial Steering Committee (TSC) or Data Monitoring Committee (DMC) (STU-SOP-TS-002) must be established. A site initiation visit (SIV) will typically be conducted after appropriate approvals are in place.

4.3 Site initiation visits

4.3.1 SIV arrangements

SIVs are required to train site staff and to review the practicalities of implementing the protocol at each site. The format of the SIV will be determined by the research project risk assessment.

The TM will organise a date for the SIV ensuring that key members of the site team are available. The risk assessment will establish if the CI should attend.

The PI and staff from all relevant departments should be invited to participate in the SIV and be available during the visit as appropriate.

For CTIMPs, the SIV will include a visit to the pharmacy and local laboratories (where required) to review Investigational Medicinal Product (IMP) and sample requirements.

4.3.2 SIV documentation and supplies

The TM will prepare an agenda (STU-AD-TMP-020) for the SIV, organise the training materials and liaise with the PI and site staff prior to the initiation visit.

The TM should confirm all relevant details of the forthcoming initiation visit in writing.

A SIV attendance log (STU-AD-TMP-021) and delegation log (STU-AD-TMP-019) will be completed during or after the SIV. The CI or authorised trainer(s) will sign off on training and attendance which the PI will countersign

The Investigator Site File (ISF) containing all research project documentation should be available at the site when the site initiation visit is conducted. The TM will ensure ISF maintenance is covered during the SIV.

For a CTIMP, IMP may be available, and should be labelled and stored appropriately until SIV completion. A pharmacy site file (PSF) should be provided.

Where research projects involve laboratories the SIV should confirm that any equipment loaned / provided for the research project is in working order. Proof of calibration and maintenance should be available as appropriate.

Any materials provided to sites such as vacutainers must be checked for their expiry date prior to issue.

4.3.3 SIV reporting

Following a SIV the TM will submit a written Site Initiation Report (STU-AD-TMP-022) to the PI and research nurse/site coordinator as appropriate for their consideration.

The site team should promptly address any outstanding actions that arose during the SIV. Major actions will require resolution prior to site activation, minor actions may be deferred to an agreed resolution date as agreed with the CI and TM. When all actions have been completed, the SIV Report can be finalised.

The completed SIV report, delegation, attendance and training logs and copies of all training materials should be filed in the Trial Master File (TMF) with copies in the ISF.

4.4 Site activation

For all research projects, the CI and TM must liaise with the Sponsor to issue a green light for site activation.

For CTIMPs, there may be a separate requirement for an IMP regulatory green light.

The CI or TM should send an ‘activate site’ email to everyone on the delegation log, requesting confirmation of receipt of the activation email.

5. References

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- UK policy framework for health and social care research (2017) -

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

- UK Medicine 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 that all subsequent amendments are included in this citation.

6. Associated Documents

Number	Title	Location
STU-AD-FRM-016	Site Expression of Interest Form	Q-Pulse
STU-AD-TMP-020	SIV Agenda Template	Q-Pulse
STU-AD-TMP-021	SIV attendance log template	Q-Pulse
STU-AD-TMP-022	Site Initiation Report Proforma	Q-Pulse
STU-AD-TMP-019	Delegation Log Template	Q-Pulse

7. Abbreviations

List of Abbreviations	
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
ISF	Investigator Site File
PI	Principal Investigator
RGF	Research Governance Framework
SIV	Site Initiation Visit
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TM	Trial Manager
TMF	Trial Master File
TSC	Trial Steering Committee

8. Appendices

Appendix 1: Document History

Version No:	3	**Effective Date:**	22-Apr-2024
Description of changes:	Update to procedure Amendment to Associated Documents Updated to SOP Template v5		