University of Hertfordshire

SITE SELECTION

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for the minimum requirements for selecting a host site for a study sponsored or co-sponsored by the University of Hertfordshire.

SOP Number: gSOP-44-01	**Effective Date:** 16th March 2022
Version Number: 1.0	**Review Date:** 3 years (or as required)

1.0 BACKGROUND

This document sets out the procedures to be followed for selecting suitable sites and conducting a feasibility assessment.

This SOP is mandatory for all UH sponsored or co-sponsored clinical trials which are regulated by the MHRA i.e. clinical trials of investigational medicinal products (CTIMPs), advanced therapy investigational medicinal products (ATIMPs) and clinical trials of medical devices which are not CE-marked or which are used outside of their CE-marked purpose (clinical investigations). For all other UH sponsored or co-sponsored studies, this SOP should be used as best practice and implemented proportionately in accordance with the risk of the study.

2.0 PURPOSE

The purpose of this SOP is to ensure that the minimum requirements for selecting suitable sites for a study sponsored or co-sponsored by UH are met and a standardised procedure is followed.

3.0 APPLICABLE TO

This applies to all staff involved in clinical research sponsored or co-sponsored by UH, including: Chief Investigators, Principal Investigators, Research Fellows, Consultants, Statisticians, Clinical Trial Pharmacists, Research Managers, Research Nurses, Clinical Trial Practitioners, Allied Health Professionals, Trial Coordinators, Clinical Studies Officers, Data Managers and Research Assistants.

4.0 RESPONSIBILITIES

4.1 The **Sponsor/Co-sponsor** is responsible for approving sites and countries to be used in the trial, taking into account the risk assessment.

4.2 Careful site selection is the responsibility of the **Chief Investigator (CI) (or delegated**

individual), who must ensure that study resources are directed to well-motivated, qualified sites with the potential to recruit eligible participants, generate high quality study data, and conduct the study within the regulations.

5.0 PROCEDURES

5.1 Conduct a feasibility assessment of any prospective sites (see associated document for guidance on how to conduct a site feasibility).

Potential sites may be identified by contacting investigators who have previous experience in the therapeutic area, recommendations by colleagues, or via publications, professional groups, or research networks. Each Principal Investigator (PI) must be qualified in education, training, and experience, which is evidenced in the form of a CV, and each site must be adequately resourced to properly conduct the study. Initial contact with a potential new site may be via an 'expression of interest' form. This is usually a brief document containing a short description of the trial, participant population, and expectation of site requirements.

A feasibility assessment must be conducted for all potential sites. As a minimum, the following items must be assessed and documented:

- Type of site (NHS or non-NHS)
- Site's willingness to participate
- Site's ability to complete all site-specific procedures
- PI training, experience, and availability
- Staff resources, and the number of PI's active trials
- Adequacy of facilities, equipment, and resources to conduct the study properly
- Availability of potential eligible participants

Details of any pre-initiation contact to assess site suitability should be documented and any issues raised must be addressed by the CI or delegate. Once information has been collected from the site, the CI should review and make a suitability decision. This process should be documented. If a feasibility assessment is deemed unnecessary, particularly if the site staff and facilities are already known to the CI or sponsor, the reason and decision for not performing a feasibility assessment must be documented in the Trial Master File (TMF).

The above process should be repeated for the selection of all new sites, throughout the study's duration.

5.2 Conduct due diligence in the selection of international sites and provide the sponsor with this information to enable the sponsor to make an informed decision.

When considering taking a trial outside of the UK, the CI must discuss this with the Sponsor/Co-sponsor. The CI should consider any limitations of indemnification of international trials. Any additional indemnification required for each country must be costed and resourced by the CI.

When research is to be conducted in countries within the EU, the CI should provide the Sponsor/Co-sponsor with sufficient justification as to why additional countries are needed outside of the UK, how they will be funded, along with a short summary of each country's clinical management. The CI should consider the resource and management implications and may consider contracting to a contract research organisation (CRO) for the management of international studies.

When research is to be conducted in countries outside of the EU, and in addition to the above, the CI and team must provide the Sponsor/Co-sponsor a short summary of the regulatory status of all countries, including differences to the EU Directive regulations and other relevant laws (for example, the Data Protection Act and the General Data Protection Regulations (GDPR)).

6.0 RELATED DOCUMENTS

- CTSN GU-10 Guidance for Conducting Site Feasibility Assessments
- CTSN TP-02 Site Feasibility Template

7.0 APPENDICES

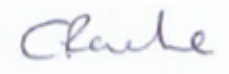
Appendix 1.0 – Definitions

8.0 VERSION HISTORY

Revision Chronology:		
Version Number	**Effective Date**	**Reason for Change**

9.0 AUTHORSHIP & APPROVAL

Author Claire Rourke

Signature  **Date** 15-Mar-22

Pro-Vice Chancellor (Research & Enterprise) Approval

Signature  **Date 01/03/2022**

10.0 AGREEMENT

I have read and understood the contents and requirements of this SOP (ref gSOP-44-01) and accept to follow University policies implementing it.

Recipient

Signature: ……Date: ……..

Name & Position: ……

Please retain copy of the signed form for your reference in your training file

Appendix 1: Definitions

Chief Investigator (CI) - A Registered Physician, Dentist, Pharmacist or Registered Nurse who has overall responsibility for the conduct of the study

Clinical Trial – A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health outcomes.

Clinical Trial of Investigational Medicinal Product (CTIMP) - A study that looks at the safety or efficacy of a medicine/food stuff/placebo in humans as defined by the Medicines for Human Use Regulations (2004). Clinical Trials are categorised as Type A, B or C.

Delegated Individual (DI)
An individual delegated by the PI to carry out their task(s).

Good Clinical Practice (GCP) - as defined in the Regulations.

Investigational Medicinal Products (IMP) - means a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial.

Principal Investigator (PI)
A Registered Physician, Dentist, Pharmacist or Registered Nurse who has responsibility for the conduct of the trial at a host site.

Sponsor's Representative
The Pro-Vice Chancellor (Research & Enterprise) will act as the Sponsor's Representative.

The Regulations
Medicines for Human Use (Clinical Trial) Regulations 2004 transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031. This became effective on the 1st May 2004. An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928.

Trial Master File
The Trial Master File (TMF) will be held at the principal site by the sponsor, Chief Investigator or at the co-ordinating Centre. The TMF should contain all essential documents defined as documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. A Trial Master File should be set up at the beginning of a trial and maintained up to date throughout the trial until trial conclusion.