UNIVERSITY OF LEICESTER

University of Leicester Research Governance Office

Standard Operating Procedures

SOP S-1033 UoL

Process for Assessing Site Feasibility for Research Sponsored by the University of Leicester (UoL)

Version 5.0, December 2024

Effective Date: February 2025

This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used. For active studies there is no requirement to update appendices to the latest version.

1.0 Introduction

This Standard Operating Procedure (SOP) defines the process to be followed when identifying sites to undertake research sponsored by the University of Leicester (UoL). A feasibility assessment is undertaken to ensure a site is able to conduct a research study in accordance with the requirements of the protocol. The aims of the feasibility assessment are to review;

- recruitment and retention strategies,
- the site facilities,
- availability of resources,
- staffing and support department(s) capacity,
- contracts and budget requirements, and
- R&D/I approval processes.

2.0 Definition

Feasibility is a process of comprehensive assessment which increases the potential for swift site specific study approvals. It helps to limit operational delays, therefore allowing a smooth transition from site Sponsor Green Light, to first patient recruited and onward delivery of the study.

A thorough feasibility assessment can identify problems needing to be addressed which may impact a site's ability to deliver the research in accordance with the protocol and/or agreement(s). It helps to identify at an early stage where issues may need to be addressed, to enable the delivery of a study at a site or, where issues are insurmountable, the exclusion of the site from being able to host the research.

3.0 Process

3.1 All studies

Investigators should undertake a Site Feasibility Assessment (SFA; Appendix 1) for all sites intending to host the research study to understand if those organisations have sufficient capacity to deliver the research. Ideally this should occur **before** adding a site to the IRAS form, as part of the initial application for Sponsorship, or **before** adding the site to an active/open study via an amendment. Organisations that have agreed in principle to host the research study should be identified on 'Part C' of the IRAS form. If additional host organisations are identified after the study has commenced, then these can be added via an amendment (refer to SOP S-1018).

It is recognised that there will be sections of the SFA that are not relevant to every study, or there may be additional aspects that need to be assessed. In these cases, the CI (or their delegate) should adapt the SFA before sending it to sites. A draft version of the SFA form is requested as part of the Application for Sponsorship in Infonetica.

The minimum information that should be provided to sites is either the version of the protocol that will be submitted for HRA and HCRW Approval (or as near a draft as possible) and/or a study summary, information about any funding allocated to the site and an overview of departments and/or staff required to support the delivery of the study at the site.

3.2 Studies using Investigational Medicinal Products (IMP) and/or Pharmacies

In addition to the SFA, where a study requires the use of Investigational Medicinal Products (IMP) – whether this is a CTIMP or non-CTIMP – a site specific Pharmacy Feasibility Assessment (PFA; Appendix 2) should also be completed and uploaded to Infonetica. The steps included in section 3.1 should be followed.

It is essential that this document be completed by a suitably qualified individual within the Pharmacy department at the site.

3.3 Process for Completing the SFA and/or PFA

1. The Chief Investigator (CI; or their delegate) must adapt the SFA accordingly and fill in the study and site information as indicated on the SFA form.
2. The Principal Investigator (PI; or their delegate) must coordinate the completion of the SFA form with input from all of the relevant support departments so as to generate an accurate assessment of feasibility.

3. The CI (or their delegate) must review the completed SFA, and make an assessment of the feasibility of the site in accordance with the following outcomes:

    - Feasible - no areas to be addressed/resolved
    - Potentially feasible* – areas to be addressed/resolved
    - Not feasible

    *Where a site is assessed as being potentially feasible, proposed changes to enable feasibility must be clearly documented and correspondence retained in the TMF. In such cases a new version of the feasibility form is not required to be completed however the original should be annotated, ideally through tracked changes, to show the changes made to support feasibility at the site.

4. Where applicable, the CI (or their delegate) should:

    a. Review any risks and provide mitigation strategies and/or
    b. Review any suggestions made by the site for protocol changes and ensure that these are discussed/addressed. If applicable/feasible, the protocol changes should be made (ensuring that this is included in the initial Application for Sponsorship, or as an amendment (whichever applies)).

5. A completed SFA for each site should be uploaded to Infonetica during the Site Sponsor Green Light request process (refer to SOP S-1025). The assessment may be discussed with the CI (or their delegate) and a decision made about whether or not it is appropriate or feasible for a site to be included.
6. Evidence of completed SFAs and Pharmacy Feasibility Assessments (PFAs) must be retained in the Trial Master File/Investigator Site File, as appropriate.

4.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator	Chief Investigator or their delegate	Undertake a Site Feasibility Assessment (SFA), and where relevant a Pharmacy Feasibility Assessment (PFA), for all proposed research sites.
Chief Investigator	Chief Investigator or their delegate	Communicate with the Sponsor and provide copies of completed SFA(s) and where relevant the PFA(s).
Principal Investigator	Principal Investigator or their delegate	Complete the SFA/PFA in collaboration with relevant support departments at their site.
Sponsor	Head of Research Governance or delegate	Complete a review of SFA/PFA and where necessary, discuss the outcome with the CI/their delegate.

5.0 Development and approval Record for this document

This table is used to track the development and approval of the document

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Sponsorship Management and Operation Group (RSMOG)	Professor Nigel Brunskill 	03/02/2025

6.0 Review Record

This table is used to track the changes made on revised/reviewed versions

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
April 2015	2	RSMOG	Minor administrative changes to text and footer, change to logos, addition of Loughborough University to front page
May 2016	3	RSMOG	Minor changes to Appendix 1 to add signature field and amendment in 4.1 to state email not letter.
Nov 2016	4	Diane Delahooke	Change of address, changed logo in appendices, consistency checks with UHL.
Sept 2021	4.1	Cat Taylor	Administrative changes
December 2024	5.0	Cat Taylor	• Administrative Changes • Removal of distribution record • Major updates to wording to provide clarity on the process and the requirement for feasibility assessments to take place for all sites involved in research. • Major updates to Appendices 1 & 2 (Site Feasibility and Pharmacy Feasibility Assessment forms)