Research Governance Office Sponsorship Standard Operating Procedures

Site Feasibility

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1.0 Introduction and Scope

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

- recruitment and retention targets and strategies,
- the facilities and resources available at the research location,
- staffing and support department(s) capacity to support the trial,
- that the location considers the funding allocated to be sufficient Whether any protocol adaptations are required to support the feasibility of the trial at the location
- Whether the location requires any additional support or equipment to conduct the trial

2.0 Definition

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

A thorough feasibility assessment can identify problems needing to be addressed which may impact a research location's ability to deliver the trial 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 trial at a research location or, where issues are insurmountable, the exclusion of the research location from being able to host the trial.

3.0 Process

3.1 All trials

The CI (or delegate) is responsible for undertaking a Site Feasibility Assessment (SFA; Appendix 1) with all research locations intending to host the trial to understand if those organisations have sufficient capacity to deliver the research. This should occur **before** adding a research location to the IRAS form, as part of the initial application for Sponsorship, or **before** adding the research location to an active/open trial via a modification. Organisations that have agreed in principle to host the research trial should be identified on 'Part C' of the IRAS form. If additional host organisations are identified after the trial has commenced, then these can be added via a modification (refer to SOP S-1018).

It is recognised that there will be sections of the SFA that are not relevant to every trial, 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. 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 potential research locations 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 trial summary, information about any funding allocated to the site and an overview of departments and/or staff required to support the delivery of the trial at the research location.

Note: Although a formal SFA is not required for Participant Identification Centres (PICs), it is recommended that the feasibility of participant identification at each PIC is discussed early in the trial planning process, as this may influence recruitment strategies and targets across other PICs and research locations.

Note: A SFA is not required for the UoL when acting as a research location.

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

In addition to the SFA, where a trial requires the use of Investigational Medicinal Products (IMP) – whether this is a CTIMP or non-CTIMP – a location specific Pharmacy Feasibility Assessment (PFA; Appendix 2) should also be completed. The process detailed 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 proposed location.

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 trial and research location 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 research location in accordance with the following outcomes:
   - Feasible - no areas to be addressed/resolved
   - Potentially feasible* – areas to be addressed/resolved
   - Not feasible

   *Where a research location 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 research location.

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 research location 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 a modification (whichever applies)).

5. A completed SFA for each research location, and where applicable a pharmacy SFA, 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 research location to be included.
6. Evidence of completed SFAs and Pharmacy Feasibility Assessments (PFAs) must be retained in the Trial Master File and Investigator Site File, as appropriate.

4.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

Date	Version Number	Description Of Changes (If Any)
April 2026	6.0	• Formatting Changes • Clarification on when a SFA isn't required • Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive. • Removal of responsibilities table as responsibilities are laid out within the body of the SOP. • Minor updates to Appendix 1 and 2, primarily as a result of terminology changes.