1. Introduction

This Standard Operating Procedure (SOP) defines the procedure to be used when identifying sites to undertake research sponsored by the University Hospitals of Leicester NHS Trust (UHL). It is essential that a feasibility assessment is undertaken by each site to ensure that they are able to conduct the research in accordance with the requirements of the protocol, and will be able to deliver the recruitment and achieve the national time and target deadlines.

2. Scope

This SOP applies to all research sponsored by the UHL. It must be used for both Single and Multisite research. It is not necessary for feasibility to be completed for Patient Identification Centres (PICs).

3. Definition

A feasibility assessment is designed to identify whether a site is able to deliver a study protocol with or without modification to organisational process. Feasibility is a process of comprehensive assessment, including risk assessment and contingency planning. Conducting a thorough feasibility assessment increases the potential for swift study approvals, and limits operational delays, therefore allowing a smooth transition from Sponsor Green Light for each site, first patient recruited within national targets, and delivery of study.
A comprehensive feasibility assessment can identify problems needing to be addressed that may have an adverse effect on the sites ability to deliver to the protocol. It helps to identify at an early stage where issues are insurmountable and therefore excludes the site from being able to participate. This enables resource to be targeted more appropriately to enable sites that can deliver, to deliver.

4. Process

4.1 All Studies

Investigators wishing to undertake research that is sponsored by the UHL must contact the Research Office at the earliest opportunity to discuss the process for site selection. The Sponsor Application and Risk Assessment process includes a requirement that each site selected to host the research has completed a Site Feasibility Assessment (SFA) - Appendix 1. SFA(s) will be reviewed and discussed as part of the Sponsor Green Light Process. A site without a completed SFA will not receive authorisation to be added as a site from the Sponsor. Studies where UHL is the single centre must also complete feasibility in collaboration with the specialty team.

The SFA allows sites to make a real time assessment about their feasibility status. There are three options to choose:

- Feasible – no further action required
- Potentially feasible – areas to be addressed / resolved
- Not feasible at this time

It is expected that the Chief Investigator (CI) will delegate an appropriate individual to manage the SFA process, and collate all responses from sites to send to the Sponsor. The SFA includes information about all support services within the sites, R&I Offices, contracts contacts and the clinical team. It is expected that an individual within the site be identified to complete the SFA on behalf of the site. This does not necessarily need to be the Principal Investigator (PI) but should be an individual with appropriate organisational knowledge.

It is recognised that there will be sections of the SFA that are not relevant to every study. In these cases, it must be made clear that the protocol does not require these sections to be completed.

When completed, the SFA must be sent to the Head of Research Operations or their delegate for review. The assessment will be discussed with the CI and a decision made about whether or not it is appropriate or feasible for the individual site to be included in the study. This decision will be communicated by email from the Sponsor to the PI, copied to the CI and site R&I/D Office.

A copy of the email and the completed SFA must be retained in the site's Investigator Site File, the CI's Trial Master File within the individual site section, and the Sponsor file. Additionally, sections 1 and 2 of the Sponsor Green Light Workflow must be completed in EDGE (Clinical Trial Management System) to indicate the SFA has been returned and completed to the satisfaction of the sponsor; this should be completed at the site (red) level. The completed SFA should be uploaded to EDGE under 'files'.

4.2 Studies using Investigational Medicinal Products (IMP)

In addition to the SFA, where a study requires the use of Investigational Medicinal Product(s) (IMP(s)), the Pharmacy Feasibility Assessment – Appendix 2 must also be completed by the Pharmacy at the site.

It is essential that this document be completed by a suitably qualified individual within the Pharmacy department at the site. Evidence of appropriateness and qualification of the individual completing the form will be required by the Sponsor. This evidence can be in the form of a CV attached to the completed Pharmacy Feasibility Assessment.

5. Non-Compliance

The aims of undertaking a feasibility assessment are to review recruitment and retention strategies, assess the sites facilities, review availability of resources; staffing, support departments, ethics and R&I approval processes and contracts and budget requirements. The burden for meeting recruitment and retention commitments are the responsibility of the investigators but also weigh heavily on the Sponsor to ensure they select sites that they think will meet the protocol requirements.

Unmet recruitment and retention targets are costly for the Sponsor but also for the sites if they commit a large amount of resources into setting up a study, only to find there are insufficient patient numbers.

There will be an automatic critical finding if it is found that a site has been added to a study without evidence of the SFA process, post 1st October 2014. The Sponsor SOP S-1016 UHL will be followed. It is likely that the study will be suspended at all sites while an investigation is carried out.

6. Responsibilities

	Responsibility	Undertaken by	Activity
1	Chief Investigator	Chief Investigator	Delegate an appropriate individual to undertake the SFA process
2	Chief Investigator	Chief Investigator or their delegate	Communicate with the Head of Research Operations and provide copies of completed SFAs.
3	Sponsor	Head of Research Operations or their delegate	Complete Sponsor Risk Assessment, Sponsor review and review of SFA. Liaise with CI and record discussion about inclusion of individual sites.
4	Sponsor	Head of Research Operations or their delegate	Confirm in writing to the PI at individual site outcome of SFA decision.
5	Sponsor	Head of Research Operations or their delegate	Manage the Pharmacy Feasibility document and confirm appropriateness of individual completing

7. Supporting Documents and Key References

SOP S-1020 Appendix 1 & 2

SOP S-1016

8. Key Words

Research, Innovation, Volunteers, Participants, CTIMPS, Trials, ICH GCP, TMF, Site Feasibility, Monitoring, TMF, PICs, SFA, Green Light, EDGE,

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This table is used to track the development and approval and dissemination of the document and any changes made on revised / reviewed versions

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Reviewed by:	R&I Governance Meeting	
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REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
September 2016	3	CM, LW, JJ	Update for HRA and consistency checks.
February 2017	4	CM	Update to Logo.
March, September 2018	5	CM, CCL, HK, JJ, LW	-Updated to reflect process within EDGE -Appendix 2 (Pharmacy) updated following comments from Helen Knight, Principal Pharmacist Clinical Trials -All documents updated to include new R&I logo -Wording updated to specify SOP is applicable to single centre as well as multicentre studies
February 2021	6	JJ LW AM	Reviewed and updated, Reformatted to new template

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