LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE
STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office
SOP–1033 LU

Process for Assessing Site Feasibility for NHS Research Sponsored by Loughborough University

Effective Date: October 2015

1.0 Introduction

This Standard Operating Procedure (SOP) defines the procedure to be used when identifying sites to undertake research sponsored by Loughborough University (LU). It is essential that a feasibility assessment is undertaken by each site (including when there is only one site i.e. only UHL) 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.

2.0 Scope

This SOP applies to all research sponsored by Loughborough University which falls within the remit of the Research Governance Framework (V2 2005). It must be used for both single and multi-site research and is effective from 1st August 2015.

3.0 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 Approval 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.

4.0 Process

Investigators wishing to undertake research that is sponsored by the LU must contact the Research Governance Officer 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 (after 1st August 2015) 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 Risk Assessment Process. A site without a completed SFA will not receive authorisation to be added as a site from the Sponsor.

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

- Feasible – no future 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&D 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 Research Governance Officer 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 letter/email from the Sponsor to the PI, copied to the CI.

A copy of the letter/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.

5.0 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&D 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 plough lots 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 August 2015. The Sponsor SOP -1016 LU will be followed. It is likely that the study will be suspended at all sites while an investigation is carried out.

6.0 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 Research Governance Manger and provide copies of completed SFAs.
3	Sponsor	Research Governance Officer	Complete Sponsor Risk Assessment and review of SFA. Liaise with CI and record discussion about inclusion of individual sites.
4	Sponsor	Research Governance Officer	Confirm in writing to the PI at individual site outcome of SFA decision.

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

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Jackie Green	**Job Title:** Research Governance Officer
Approved by:	Ethics Committee	**Date Approved: 23/10/15**

REVIEW RECORD			
Date	**Issue No.**	**Reviewed By**	**Description Of Changes (If Any)**

DISTRIBUTION RECORD:			
Date	**Name**	**Dept**	**Received**

Study Feasibility Assessment

A robust feasibility is an essential part of ensuring study delivery. Please pass this Study Feasibility Assessment and a copy of the protocol to the individual(s) who are most appropriate to accurately complete the form.

Appended to this SFA should be the latest version of the protocol and information about any funding allocated to your site.

Any queries, please contact the study coordinator or the Research Governance Officer.

Site Name: **Site Reference No:** (if applicable) Point of Contact Name: (if different to PI) POC Email: POC Phone No:		**PI Name:** **PI Email Address:** **PI Phone No:**
Research & Development : Contact Name: Email address: Phone Number:		**Contracts Contacts:** Contact Name: Email address: Phone Number:
Postal Address for Research & Development:		**Registered Address for inclusion in the contract:**
Pharmacy : Contact Name: Email address: Phone Number:		**Radiology :** Contact Name: Email address: Phone Number:
Laboratories : Contact Name: Email address: Phone Number:		**Medical Physics :** Contact Name: Email address: Phone Number:
Recruitment Target for Site:		

Feasibility Assessment Line of Questioning	Site Response – Please add your comments to the question in the box below. Please answer every question. If Not Applicable please state N/A	Site Assessment – please indicate your current feasibility status by answering 1,2 or 3: 1 – Feasible 2 – Potentially Feasible 3 – Not Feasible at this time
Is there anything in the protocol which is non-standard for your organisation?		
Is there anything in the protocol that you consider ambiguous and that needs to be explained in greater detail?		
Are there any procedures within the protocol that require early or additional support from support departments?		
Are there several procedures within narrow timelines required? If so, are your support departments, i.e. Labs / Radiology aware and prepared for this?		
Funding		
Have funds been allocated to your site?		
Are they adequate for you to deliver the research in line with the protocol?		
Will an application be made to the LRN for support costs (where appropriate)?		

Resource		
Who will be working on the study? Please list names of individuals and their role as it will appear on the Delegation Log.		
Does the study team have previous experience of running this type of trial? If not, what training do they require?		
Is there a back-up co-investigator? This person must be appropriately qualified to sign SAE forms in the absence of the CI and must be delegated appropriately on the Delegation Log.		
Who will be taking consent? Are they appropriately qualified to take consent? Has consent training been delivered? (where appropriate)		
Do site staff have sufficient resource?		
How many studies are currently being run by the department?		
Are there any studies competing for the same patient population?		
Facilities		

Does the site have adequate facilities & equipment to accommodate the study? - Patient/research area - Blood pressure machine - ECG - Freezer - Fridge - Centrifuge - Centrifuge calibration - Temperature Monitoring - Water bath Any study related equipment not listed here but included in the protocol.		
If not, how will the site access facilities/equipment?		
Other support departments: Which support departments will be required to conduct the study? NB Where pharmacy is required a separate pharmacy feasibility document must be completed.		
Recruitment		
Were previous recruitment targets met for other similar studies?		
Does the protocol recruitment strategy fit with your sites Patient Pathway?		
Who will be responsible for driving recruitment at the site?		

Who will be responsible for reporting recruitment at the site? (if different to above)		
Do you foresee any potential problems with recruitment at your site?		
Can you meet the recruitment timelines and targets?		
What is your current metric on meeting the recruitment targets? (70day target%)		
Are there any seasonal issues that may affect recruitment at your site?		
Governance		
Has everyone got an up-to-date CV and GCP training certificate?		
Who will be responsible for ensuring site file is kept inspection-ready?		
Where are files and study related documents stored? Where will Site Files be archived at the end of the study?		
Comments		