Plymouth Research and Development

University Hospitals Plymouth NHS Trust

Standard Operating Procedure

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Title:	Feasibility and site selection		
Approver		Document No:	P1
Name:	Chris Rollinson	Version No:	2.0
Signature:		Effective Date:	Jul-2022
Date:	01-Jul-2022	Review Date:	Jul-2025

1. Purpose

To describe the procedure for study site feasibility and site selection to ensure a study can be delivered safely and effectively. Study site setup and obtaining regulatory approvals is not described here, refer to Standard Operating Procedure (SOP) P3.

2. Scope

This SOP relates to all research studies hosted, and/ or sponsored by University Hospitals Plymouth (UHP).

3. Responsibilities

Sponsor is responsible for selecting appropriate Principal Investigator (PI) sites to conduct research studies. This task maybe delegated to the Chief Investigator (CI) and/ or Clinical Trials Unit (CTU).

Research Governance Manager (RGM) and Deputy RGM act on behalf of the Trust where it is the study Sponsor.

Chief Investigator or delegate is responsible for assessing the suitability of investigator sites for their study, filing the completed feasibility assessment documentation in the Trial Master File (TMF) and informing the site of the outcome of the feasibility assessment process.

Research and Development (R&D) Operations Team is responsible for logging all feasibility requests and liaising with the Clinical Delivery Team and Sponsor or delegate.

PI in collaboration with the Research Nurse Specialist (RNS) is responsible for feasibility assessment and responding to in a timely manner.

4. Documents needed for this SOP

- None

5. Related documents

- SOP P3 Study site setup and regulatory approvals

6. Acronyms

CDA: Confidentiality Disclosure Agreement

CI: Chief Investigator

CTU: Clinical Trials Unit

EoI: Expression of Interest

PI: Principal Investigator

R&D: Research and Development

RGM: Research Governance Manager

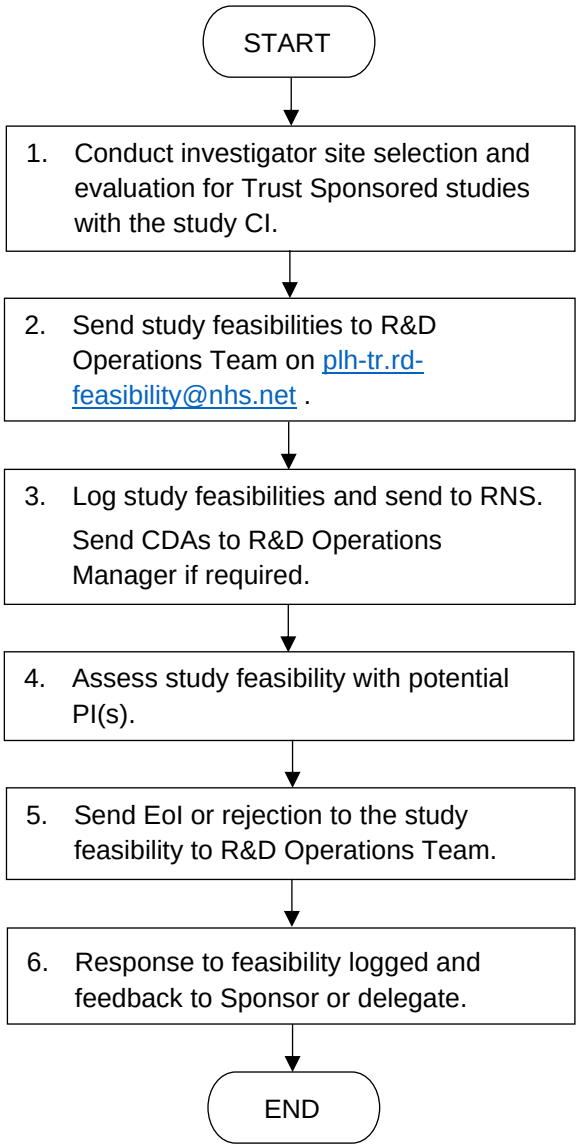
RNS: Research Nurse Specialist

SOP: Standard Operating Procedures

TMF: Trial Master File

UHP: University Hospitals Plymouth

7. Process map(s)/ flow chart(s)



8. Procedure

Step	Action	Responsibility

1	Consider factors that should influence investigator site selection and evaluation for multi-centre Trust sponsored studies:
	• Interest in the research question
	• Experience and qualifications of the investigator
	• Sufficient staff to conduct the study and their experience and qualifications
	• Availability of suitable patient population:
	  ○ Anticipated recruitment rate
	  ○ Conflicting studies
	  ○ Adequate time to conduct and oversee the study
	• Adequate facilities:
	  ○ Availability of specialised diagnostic or therapeutic equipment
	  ○ Adequate space and storage conditions
	  ○ Available resources in NHS support departments
	• Track record with similar studies previously
	• Geographic location
	• Contractual and budgetary negotiations and arrangements
	Undertake site selection, including 'reserve' investigator sites so the study may be extended to these sites if recruitment issues arise.
		RGM, Deputy RGM or delegate.

2	Send study feasibilities to R&D Operations Team on plh-tr.rd-feasibility@nhs.net at earliest opportunity with at least the minimum information required to assess: • timeline to include planned recruitment start and end date, planned end of study; and • study synopsis with basic inclusion and exclusion criteria	Sponsor or delegate.
3	Log feasibility request and send to the Research Nurse Specialist (RNS) for the speciality. Send feasibilities involving large recruitment numbers to R&D Operations Director. Occasionally Confidential Disclosure Agreements (CDAs) may precede a feasibility, these should be sent to the R&D Operations Director for review and sign off.	R&D Operations Team.

Step	Action	Responsibility
	Requests for a Local List Review maybe received where sponsors are scoping which sites may be interested in a study type (these are not full studies). These requests should not be logged as feasibilities.	
4	Identify potential PI(s) and forward feasibility request for consideration. When undertaking a feasibility, it is important to assess: • Workforce capability and capacity • Clinical Support Service(s) capacity, capability and equipment • Do you have the correct pool of patients? • Is it deliverable/ realistic? • Does it compete with any other studies? • Which is the right fit? • Do you have the right equipment/ facilities? • Are there any other factors that might affect your ability to deliver? i.e. adjacent site • Is the clinical protocol/ synopsis consistent across documentation, and consistent with Standard of Care practice unless new practice is the point? If not, there could be chance of high deviation.	RNS and PI.
5	Response to the feasibility from PI within a reasonable timeframe i.e. 30 days from receipt of RNS. If no response, feasibility will be declined. Send Expression of Interest (EoI) and confirmation study is feasible to the R&D Operations Team with completed feasibility questionnaire, where applicable. EoI does not commit the investigator to the study. Rejection of a feasibility must be accompanied by a reason.	RSN and PI.
6	Contact Sponsor or delegate with response to feasibility and where applicable completed questionnaire. Response to feasibility logged including date returned to Sponsor or delegate.	R&D Operations Team.
	Send confirmation of site selection to R&D Operations Team, PI and RNS or, if required request Site Selection Visit (SSV).	Sponsor or delegate.

9. Changes from last revision

SOP template change and major revision to the feasibility and site selection procedure.