

**Document Title: Site Selection and Initiation for  
RF Sponsored Studies**

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SOP 26: Site Selection and Initiation for RF Sponsored Studies

V2 26 SEPT 2017

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**Version Control**

Version	Date	Author	Status	Comment
1	30 SEPT 2014	Heidi Saunders	Final	New Document
1.1	03 OCT 2017	Lucy Parker	Final	SOP Review Date Time Extension
2	26 SEPT 2017	Lucy Parker	Final	Update to new template Addition of suggested checklist document. Removal of references to IMP Change from the Sponsor providing packs to sites to the CI or a member of their team providing packs to sites. Removal of SSI references and addition of HRA approval Removal of mandatory GCP training Updated from Research Governance Framework for Health and Social care (2005) to UK Policy Framework for Health and Social Care (2017)

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## 1. INTRODUCTION

This document sets out the procedures to be followed by all Royal Free London staff who are involved in the selection and initiation of investigator sites (from now on referred to as 'sites') for RF sponsored research studies.

It aims to provide clear guidance on the steps involved in the selection of sites, the assessment and initiation of a site, and who is responsible for obtaining the local approvals necessary for a study to commence, to ensure compliance with the Trust's policies.

## 2. OBJECTIVE

This SOP outlines the minimum requirements for opening a site for a RF sponsored study, and describes the procedure for the selection of suitable sites and for conducting site initiation and activation for trials. For RFL sponsored non-CTIMP studies, this SOP should be used as best practice and implemented proportionately for all sponsored studies. The purpose is to ensure that:

- All essential documentation, approved protocol, SOPs, and required approvals are in place prior to the start of the trial at a site.
- All staff members at each site are aware of their responsibilities, the Sponsor processes, and SOPs.
- The site team are appropriately trained and experienced and that they have GCP training which is current and documented.
- The 'delegation of tasks' log is completed before any trial related activities are performed, and that all individuals are authorized by the PI to undertake such tasks.
- To ensure that the site, Sponsor, and coordination team contact details are up to date and correct, and that the site know how to contact the Sponsor.

## 3. DEFINITIONS

**RF** - Royal Free London Hospital NHS Foundation Trust

**RM&G** - Research Management & Governance

**R&D** - Research & Development

**Clinical Trial of Investigational Medicinal Product (CTIMP)** - Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal products(s) and/or Study absorption, distribution, metabolism and excretion of one or more investigational product(s) with the object of ascertaining its (their) safety and/or efficacy.

**Sponsor** - Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make

arrangements to allocate all the responsibilities in this research governance framework that are relevant to the study.

**CI** - Chief Investigator (CI) is the authorised health care professional who takes primary responsibility for the conduct of the trial. There is only one Chief Investigator per Member State.

**PI** - Principal Investigator (PI) is the person who takes responsibility for the initiation and conduct of the study at site. There is one Principal Investigator at each site participating in a research study. For a single site study the Chief investigator may also take on the role of Principal investigator

**GCP** - Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

#### **4. SCOPE**

The Royal Free London Hospital NHS Foundation Trust does not Sponsor CTIMPs. Therefore, this SOP will only cover selection and initiation of non CTIMP studies.

This SOP covers the procedures that must be followed to ensure that a site is initiated prior to the screening and recruitment of any trial participant. It covers the procedures before initiation (including site selection), during the site initiation, and post-initiation to activate the site to begin the trial.

The CI is responsible for site selection, site initiation, and site activation in the Conditions of Sponsorship (in the delegation of responsibilities), by ensuring that all documentation is in an appropriate and secure location. It is recognised that this responsibility may be delegated to another member of the research team with sufficient knowledge and training.

Therefore, for the purposes of this SOP, reference to the CI shall be deemed to also refer to the individual with delegated responsibilities for these activities.

#### **5. EQUALITY STATEMENT**

The Royal Free London NHS Foundation Trust is committed to creating a positive culture of respect for all individuals, including job applicants, employees, patients, their families and carers as well as community partners. The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability (including HIV status), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. It is also intended to use the Human Rights Act 1998 to treat fairly and value equality of opportunity regardless of socio-economic status, domestic circumstances, employment status, political affiliation or trade union membership, and to promote positive practice and value the diversity of all individuals and communities.

This document forms part of the trust's commitment. You are responsible for ensuring that the trust's policies, procedures and obligation in respect of promoting equality and diversity are adhered to in relation to both staff and service delivery.

The equality analysis for this SOP is attached at Appendix (2).

## 6. DUTIES

The Trust is committed to the delivery of world class care and expertise to both staff and patients, and our values of positively welcoming, actively respectful, visibly reassuring and clearly communicating are fundamental to the delivery of this. This policy has been developed with our values in mind, and is intended to be implemented within the spirit of these values.

This SOP applies to any appropriately qualified member of the trial team who will be responsible for identifying and selecting suitable sites and informing them of trial procedures.

Site selection and site initiation are usually part of the Trial Coordinator or Trial Manager's role with advice and support of the Chief Investigator (CI). The person responsible should follow the procedures as detailed in Section 7.

## 7. DETAILS OF THE PROCEDURE

Person Responsible	Task
CI	<p><b>7.1 Site Selection</b></p> <p>The Chief Investigator (CI) is responsible for selecting appropriate sites for a particular study although this task may be delegated to a member of the study team.</p> <p>The number of sites and location must be agreed as part of the Sponsorship approval process. The number of sites in the UK must be agreed with the Sponsor (research portfolio manager). The Sponsor reserves the right to cap the number of sites, depending on the level of resource and on-going compliance of the trial.</p> <p>Potential sites may be identified by contacting investigators who have previous experience in the therapeutic area, recommendations by colleagues, or via publications, professional groups or research networks.</p> <p>If potential investigators/sites indicate an interest in the trial, the site's suitability, interest and willingness to participate in the study will be assessed.</p> <p>Details of any pre-initiation contact to assess site suitability should be documented and any issues raised must be addressed by the CI or delegate.</p> <p>Once information has been collected from the site, the CI should review and make a suitability decision. This process should be documented. If a feasibility assessment is deemed unnecessary, particularly if the site staff and facilities are</p>

	<p>already known to the CI or Sponsor, the reason and decision for not performing a feasibility assessment must be documented in the TMF.</p> <p>Each PI must demonstrate by education, training and experience that they are suitable to lead the study at their site and they must have adequate resources to properly conduct the study. This must be evidenced in the form of a current curriculum vitae (CV) or other documentation and stored in the trial master file (TMF).</p> <p>Factors that should be considered during investigator site selection include:</p> <ul style="list-style-type: none"> <li>• Interest in the research question</li> <li>• Experience and qualifications of the investigator</li> <li>• Ability to comply with the trial protocol</li> <li>• Sufficient suitably qualified and experienced staff to conduct the study</li> <li>• Availability of suitable patient population:             <ul style="list-style-type: none"> <li>○ Anticipated rate of patient recruitment</li> <li>○ Conflicting studies (competing for the patient population and potentially introducing recruitment bias)</li> </ul> </li> <li>• Adequate time to conduct and oversee the trial</li> <li>• Suitable facilities:             <ul style="list-style-type: none"> <li>○ Availability of any specialised diagnostic or therapeutic equipment required by the protocol</li> <li>○ Satisfactory space and storage conditions (including archive)</li> </ul> </li> <li>• Available resources in NHS support departments</li> <li>• Track record of recruiting</li> <li>• Geographic location</li> <li>• Contractual and budgetary negotiations and arrangements.</li> </ul> <p>The site selection process and rationale for selection of a particular site must be documented and stored in the TMF.</p> <p>The site selection process should also consider trial restrictions or limitations (for example, funds available for site visits). When undertaking site selection, the preparation of 'reserve' investigator sites should be considered as part of proactive trial planning (so that the trial may be extended to these sites if recruitment issues arise).</p> <p>A suggested site feasibility checklist is available from the RF R&amp;D Office website (RFLRDDOC0010). The CI must request completion of the checklist by the PI.</p> <p>Request all site essential documentation from individual sites. Request the following documents from each site:</p>
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	<ul style="list-style-type: none"> <li>• Site Confirmation of capacity</li> <li>• Fully signed Agreement (if applicable)</li> <li>• Copy of the PI's signed CV and GCP certificate</li> <li>• Completed delegation log</li> <li>• Completed site feasibility questionnaire</li> </ul>
<p>CI</p>	<p><b>7.2 Site set up</b></p> <p>Following confirmation of suitability as a site, the CI or a delegated member of their team will provide the site with all the necessary documents and information to allow the site to obtain local R&amp;D approval.</p> <p>The following documentation should be in place at the trial site prior to the site being opened to recruitment</p> <ul style="list-style-type: none"> <li>• CI/PI signed and dated acceptance of responsibilities</li> <li>• Evidence of financial arrangements</li> <li>• Appropriate Insurance to cover the whole study period</li> <li>• Unconditional written approval from a relevant Research Ethics Committee for the protocol and essential documents.</li> <li>• Unconditional written approval from the HRA</li> <li>• Principal Investigator's (PI) CV</li> <li>• Signed agreement by all parties</li> <li>• NHS permission for the particular site</li> <li>• Any additional essential approvals (e.g. ARSAC)</li> <li>• Appropriately signed Delegation of Responsibilities log (Suggested RFLRDLOG0004)</li> <li>• Documented evidence of site training e.g. initiation visit</li> </ul>
<p>CI</p>	<p><b>7.3 Site Initiation</b></p> <p>When a site is close to receiving all the necessary approvals, a mutually convenient time for the initiation should be arranged. The initiation may be conducted by a site visit, teleconference, by giving detailed written instructions or at a trial launch meeting. The process will depend on the complexity of the trial and the previous trials experience of the site. If it is difficult to arrange a time for all site staff to be present, more than one meeting or telephone conference could be arranged with the site.</p> <p>The CI is responsible for site initiation and this may be delegated to a member of the research study team. A template SIV PowerPoint presentation is available from the RF R&amp;D Office (RFLRDDOC0031)</p> <p>The person delegated by the CI to conduct the SIV should</p>

	<p>be thoroughly trained in the trial and protocol, including having a good understanding of all trial procedures, CRFs, expected AEs, un-blinding procedures, randomisation, Sponsor and study specific SOPs. This should be documented and reflected on the delegation log</p> <p>Site initiation must be completed prior to the site opening to recruitment (before any trial related procedures are carried out).</p> <p>The initiation should include the PI, other co-investigators, research nurses and any other member of staff who will be involved with trial related activities. Each study activity covered in the initiation must be discussed with at least one member of the study team who has been delegated responsibility for the activity.</p> <p>The agenda for discussion should include (as appropriate):</p> <ul style="list-style-type: none"> <li>• Study design – objectives and assessments</li> <li>• Study intervention / specific procedures</li> <li>• Timelines and recruitment targets</li> <li>• Informed consent process</li> <li>• Identifying, registering and randomising participants</li> <li>• Adverse Event (AE) and Serious Adverse Event (SAE) recording / reporting procedures</li> <li>• Responsibilities – to be documented on the site signature and delegation log (RFLRDLOG0004)</li> <li>• Laboratory issues</li> <li>• Case Report Form (CRF) completion, storage and security – including the use of self-evident corrections by trial data management staff when appropriate</li> <li>• Investigator Site File (ISF) maintenance (SOP019)</li> <li>• Other departments involvement e.g. pathology, radiology</li> <li>• Monitoring and auditing procedures</li> <li>• Study milestones</li> <li>• Investigator Site File contents (SOP019)</li> <li>• Provisions for archiving trial data at the end of the trial (SOP044)</li> <li>• Any outstanding issues / concerns.</li> </ul> <p>The training must include:</p> <ul style="list-style-type: none"> <li>• Sample chain of custody process and logs, shipment as appropriate. Where appropriate a visit and review of any sample processing or storage areas.</li> <li>• End of Trial and archiving;</li> <li>• Procedure for PI cover during any absence</li> <li>• Training the team of study specific software, equipment, or devices, including the requirements for calibration and verification before the study starts, and maintenance once the study is open</li> </ul>
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	<p>Post the initiation visit, the CI must also ensure:</p> <ul style="list-style-type: none"> <li>• Test scans (if applicable; e.g. MRI), have been performed, and the quality and transfer has been deemed acceptable</li> <li>• Site has received e-CRF or CRF training, which should include clear guidelines as to when the CRF should be completed and authorised by PI and how problems are escalated.</li> </ul>
CI	<p><b>7.4 Post initiation</b></p> <p>A letter (or email) should be sent to the site to summarise the meeting / teleconference. The letter should state who attended the meeting, what issues were discussed, questions raised with responses showing resolution and whether or not the site is now ready to start recruitment.</p> <p>The original initiation meeting letter should be filed in the TMF.</p>
PI at site	<p><b>7.4 Post initiation</b></p> <p>The original initiation meeting letter should be filed in the Investigator Site File (ISF)</p>

## 8. POLICY

This SOP is mandatory and non-compliance with it may result in disciplinary procedures.

## 9. RISK MANAGEMENT/ LIABILITY/MONITORING & AUDIT

- The SOP Working Group will ensure that this SOP and any future changes to this document are adequately disseminated.
- The R&D Office will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).
- In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the RM&G Manager/Deputy R&D Director should be gained before any action is taken.
- SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.
- The R&D Office is responsible for the ratification of this procedure.

**10. FORMS/TEMPLATES TO BE USED**

RFLRDDOC0010 Site Feasibility Checklist

RFLRDLOG0004 Staff Delegation of Duties Log

**11. FLOWCHART**

NA



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**APPENDIX 2**

**Royal Free London NHS Foundation Trust Equality Analysis guide and Tool**

An equality analysis is a review of a policy, practice, function, business case, project or service change which establishes whether there is a negative effect or impact on particular social groups. This In turn enables the organisation to demonstrate it does not discriminate and, where possible, it promotes equality to meet the needs of the diverse patients and communities we serve.

This check list is a way to help you think carefully about the likely impact on equality groups and take action to improve services. This is also an opportunity to evidence positive practices in our services and demonstrate strategic integrity to ensure that our services and employment practices are fair, accessible and appropriate for all patients, visitors and carers, as well as our talented and diverse workforce.

Name of the policy / function / service development being assessed	SOP on site selection and initiation for RF Sponsored studies
Briefly describe its aims and objectives:	This SOP outlines the minimum requirements for opening a site for a RF sponsored study, and describes the procedure for the selection of suitable sites and for conducting site initiation and activation for trials.
Directorate and Lead:	Rachel Fay, R&D Manager
Evidence sources: DH, legislation. JSNA, audits, patient and staff feedback	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care (2017)
Is the Trust Equality Statement present?	Yes    X                      No    if no do not proceed with Equality Analysis (EA)

If you are conducting an EA on a procedural document please identify evidence sources and references, who has been involved in the development of the document, process or strategy, and identify positive or negative impacts. It is the discussion regarding the equality impact of the document that is important.

### Equality Analysis Checklist

Go through each protected characteristic below and consider whether the policy, practice, function, business case, project or service change could have any impact on groups from the identified protected characteristic, involve service users where possible and get their opinion, use demographic / census data (available from public health and other sources), surveys (past or maybe carry one out), talk to staff in PALS and Complaints and Patient Experience.

Please ensure any remedial actions are Specific, Measureable, Achievable, Realistic, and Timely (SMART).

Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
<b>Age</b>	None identified	R&D administrative document	N/A	N/A	This SOP on site selection and initiation for RF Sponsored studies introduces a requirement to include the Trust Equality Statement in all SOPs that describe the standard activities used in Research Studies and Clinical Trials at the Royal Free London Hospital NHS Foundation Trust.
<b>Disability</b>	None identified	R&D administrative document	N/A	N/A	
<b>Gender Reassignment</b>	None identified	R&D administrative document	N/A	N/A	
<b>Marriage and Civil Partnership</b>	None identified	R&D administrative document	N/A	N/A	
<b>Pregnancy and maternity</b>	None identified	R&D administrative document	N/A	N/A	
<b>Race</b>	None identified	R&D administrative	N/A	N/A	

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Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
		document			It also introduces a new Equality Analysis Template for the SOPs, that requires the presence of the Equality statement.  These actions are designed to embed the equality agenda and promote equality compliance within the Trust.
<b>Religion or Belief</b>	None identified	R&D administrative document	N/A	N/A	
<b>Sex</b>	None identified	R&D administrative document	N/A	N/A	
<b>Sexual Orientation</b>	None identified	R&D administrative document	N/A	N/A	
<b>Carers</b>	None identified	R&D administrative document	N/A	N/A	

It is important to record the names of everyone who has contributed to the policy, practice, function, business case, project or service change.

Equality Analysis completed by: (please include every person who has read or commented and approval committee(s). Add more lines if necessary)	Organisation	Date
SOP Working Group	Royal Free London NHS Foundation Trust	20/10/2017
R&D Committee	Royal Free London NHS Foundation Trust	30/11/2017

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