

**Document Title: Participant Recruitment Process**

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**Version Control**

Version	Date	Author	Status	Comment
1	01/07/2014	Rachel Ochiel, Lead Research Nurse (MSK) / Anita Amadi	Final	New Document
1.1	03/10/2017	Lucy Parker	Final	SOP Review Date Time Extension
2	16/11/2017	Rachel Ochiel	Final	<p>Update to New SOP template.</p> <p>Change from Research Governance Framework to UK Policy Framework for Health and Social Care (2017)</p> <p>Addition of references to EDGE</p> <p>Change from references to subjects to participants</p> <p>Include the requirement to document in the source data giving the PIS to participant prior to the screening visit</p> <p>Include requirement, specifically for any subjects that transfer to the site, to adequately document any discussions with the original PI/site, file any correspondence received from the original PI/site, and contact the original PI/site should any queries, questions, concerns, etc. be raised on the data originating from the original site.</p>



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## 1. INTRODUCTION

Recruitment in the context of a research study is the process by which a suitable participant is identified as being eligible for a clinical trial. In order for such eligibility to be determined the participant must meet certain study specific criteria as determined by the approved protocol.

This process applies to all Royal Free clinical research staff involved in recruitment tasks in clinical trials/ studies at Royal Free.

## 2. OBJECTIVE

To describe the process involved in recruiting participants for participation in clinical trials/ studies according to the inclusion and exclusion criteria outlined in the protocol.

## 3. DEFINITIONS

RF Royal Free London NHS Foundation Trust

PI Principal Investigator

CI Chief Investigator

ICH-GCP International Council of Harmonisation of Good Clinical Practice

WI Work Instructions

## 4. SCOPE

This Standard Operating Procedure (SOP) describes the process for recruiting participants onto a clinical research study. It outlines the procedures for screening, enrolment and reporting recruitment.

## 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.

The Principal Investigator (PI) is responsible for the recruitment process. Where they delegate the duty of recruiting participants into a study, they are responsible for ensuring that the delegation of this duty is appropriate and the person delegated the role is qualified to do so by their qualifications, training and experience.

The role of recruiting participants can be delegated from the PI to a Research Nurse (RN) or a clinical trial practitioner where it is appropriate and where the RN/Clinical Trial Practitioner accepts the delegation.

The PI or CI can identify eligible participants to enrol onto a trial/ study. This task can also be delegated to Co-Investigators or RNs at the discretion of the PI/ CI. The PI has overall responsibility to ensure that the study:

- Recruit to agreed time and target
- First participant is recruited within 70 days from the receipt of the valid research application and that this is notified to RF R&D.
- Participant recruitment is recorded on EDGE. This is irrespective of whether the study is on the NIHR portfolio or not.

## 7. PROCEDURE

Person Responsible	Task
PI or delegated study Team member	<p><b>7.1 Participant Screening</b></p> <p>Before any initial contact is made with a participant with regards to a trial a full eligibility check should be performed. Training on eligibility criteria should be provided by the Sponsor, PI or any other suitable member of the research team.</p> <p>Protocol Training received should be documented in the training logs held within the Investigator Site File (ISF) held at the site. (See SOP0004 – Training Records)</p>

	<p>Using all available and reliable sources of information pertaining to a particular participant such as case files or electronic databases, the researcher should cross check all details with the inclusion/exclusion criteria of the relevant study which can be found in the protocol. These criteria can take a number of factors into account.</p> <p>Participants can be excluded on the basis of demographic information such as age, on the particularities of their condition(s) or medical history, on the treatments they are currently receiving or have received in the past and myriad other factors. Summary sheets can be created detailing the exclusion/inclusion criteria in order to make identifying participants easier. It must be ensured that the most recent approved version of the protocol is being used to perform this task.</p> <p><b>The PI, research delivery team or delegate should document in the source data e. medical notes when the participant was given the participant information sheet and any discussions to demonstrate that the participant were given ample time to consider the information and their participation in the trial prior to attending their screening visit.</b></p> <p>If all available evidence points to the participant being eligible they can be contacted by phone or email in order to obtain more detailed information than what is documented in the notes or on databases.</p> <p>Participants should be provided with the most recently approved Participant Information Sheet to read and discuss with family and their doctors (either their doctors within the hospital or with their GP) should they wish to.</p> <p>This initial contact should be recorded in the patient's medical notes. If the initial contact was via email, the email should be printed off and placed in the patient's medical notes.</p> <p>Pre-screen logs should be updated and maintained in order to keep track of which participants have been excluded and on what basis and to record all trial related activity.</p>
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	<p>If, upon contact, participants choose not to take part in the study all efforts should be made to find out why and documented on this log as this can be used for future amendments. However, participants do not have to inform the study team as to why they did not want to take part if they choose not to.</p> <p>If participants agree, they should be booked for a screening visit where all necessary information is collected in order to finalise their eligibility status. However no trial specific procedures should be carried out until after consent.</p> <p>Once eligibility is confirmed this should be clearly documented in the medial notes that the participant is to take part in the study.</p> <p>Screening logs provided by the Sponsor should be kept up to date throughout the recruitment window.</p>
<p>PI or delegated study Team member</p>	<p><b>7.2 Enrolment</b></p> <p>Once a participant participant has signed the consent form, they should be given a copy of the participant information sheet and a copy of the consent form to keep. This must be the current approved version and must also be on locally headed paper.</p> <p>For more information on the informed consenting process, depending on the patient group being recruited, please refer to:</p> <p>SOP007 – Informed Consent – Adults,  SOP008 – Informed Consent – Children  SOP009 – Informed Consent – Adults who Lack Capacity</p>
<p>PI or delegated study Team member</p>	<p><b>Transferring participants already on the study from other sites to RFL</b></p> <p>If a participant is already enrolled on the study at another site (other NHS trust, or non-NHS site) but is being transferred to the RFL site there is a requirement, to adequately document any discussions with the original PI/site, file any correspondence received from the original PI/site, and contact the original PI/site should any queries, questions, concerns, etc. be raised on the data originating from the original site.</p> <p>Queries relating to the participant prior to the transfer will be resolved by the originating site’s PI. But once transferred to RFL the research queries will be the responsibility of the RFL PI.</p>



<p>PI or delegated study Team member</p>	<p><b>7.3 Reporting Recruitment</b></p> <p>Once the participant has signed the consent form, any further trial specific tests can be carried out.</p> <p>If these all confirm eligibility then the participant can be registered onto the research study. The researcher should refer to the protocol for the registration / randomisation process.</p> <p>The study specific recruitment log should be completed and maintained within the site file.</p> <p>The study team must have a named individual who is responsible for uploading recruitment figures onto EDGE and answering RF R&amp;D Office queries on recruitment numbers. (see Section 7.5)</p>
<p>PI or delegated study Team member</p>	<p><b>7.4 Participants Who do not Speak English (RF Site)</b></p> <p>When recruiting participants who do not speak English please refer to the IRAS form on whether the study allows non-English speaking participants to participate (A33-1)</p> <p>The interpreting service exists for participants who speak little or no English and who require communication support. All requests for interpreting are managed by the Patient Advice and Liaison (PALS) team. The office is located on the ground floor of the main RFL building, next to main reception. The service uses external agencies to provide both face-to-face and telephone interpreting. Telephone interpreting should be used for all appointments 40 minutes or under where participants are assessed on an individual basis.</p> <p>To use telephone interpreting please call 0800 028 0073, provide the operator with details of the service booking the interpreter together with the language, your details and the ID code 269237. You will be connected to an interpreter within 40 seconds.</p> <p>Face-to-face interpreters have to be booked five working days in advance as interpreters are not employed direct by the trust. Please note that all face-to-face booking must be made through PALS and not with the interpreter or agency direct. However, it is worth checking with PALS whether an interpreter is possible even if the timeframe is less than 5 working days. Please confirm with sponsor prior to booking face-to-face interpreters.</p> <p>Please note that the PALS department closes at 5pm therefore any bookings received after 4.30pm that day if cancelling a booking then please e-mail the details to</p>

	<p><a href="mailto:rf.PALS@nhs.net">rf.PALS@nhs.net</a>. The PALS office is closed at weekends and request forms submitted after 4pm on Friday will not be processed until the following Monday (excluding Bank Holidays).</p>
	<p><b>7.5 EDGE</b></p> <p>EDGE is the R&amp;D research database used for recording the number of participants being enrolled into studies being run at a Royal Free site. Each study being run at a Royal Free site must have a named person responsible for uploading the recruitment figures onto EDGE. This person is known as the accrual contact.</p> <p>The accrual contact must have an EDGE user account and undergo training in how to use the system. This can be arranged through emailing the generic RF R&amp;D email account <a href="mailto:rf.randd@nhs.net">rf.randd@nhs.net</a> for the attention of the R&amp;D Research Data and Performance Analyst</p> <p>The accrual contact working on the study is required to enter the minimum data set for each participant. The minimum data set requirements can be found in the EDGE User Guide on the RF R&amp;D Office website <a href="http://www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/">www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/</a></p> <p>It is expected that staff seeing participants will be required to upload data by the end of that working week e.g. If a participant is seen on a Friday they would have 5 working days to upload the data. It is very important that this is completed on time as delays may impact the funding the Royal Free receives from the CRN. This will be monitored on a regular basis to check that the data is up to date. The R&amp;D Research Data and Performance Analyst will chase for missing data. If chasing emails are not answered, it will be escalated to the Theme lead for that study.</p> <p>It will be the responsibility of the R&amp;D department to request access to new studies on EDGE that will be taking place at the Royal Free London NHS Foundation Trust.</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 R&D 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**

NA

**11. FLOWCHART**

None applicable



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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	Participant recruitment process
Briefly describe its aims and objectives:	The process of recruiting participants into research studies
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?	<b>Yes</b> 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).

<b>Equality Group</b>	<b>Identify negative impacts</b>	<b>What evidence, engagement or audit has been used?</b>	<b>How will you address the issues identified?</b>	<b>Identifies who will lead the work for the changes required and when?</b>	<b>Please list positive impacts and existing support structures</b>
<b>Age</b>	None identified	R&D administrative document	NA	NA	This SOP includes the Trust Equality Statement, as well as the results from the Equality Assessment for this SOP.  These actions are designed to embed the equality agenda and promote equality compliance within the Trust.
<b>Disability</b>	None identified	R&D administrative document	NA	NA	
<b>Gender Reassignment</b>	None identified	R&D administrative document	NA	NA	
<b>Marriage and Civil Partnership</b>	None identified	R&D administrative document	NA	NA	
<b>Pregnancy and maternity</b>	None identified	R&D administrative document	NA	NA	
<b>Race</b>	None identified	R&D administrative	NA	NA	



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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			
<b>Religion or Belief</b>	None identified	R&D administrative document	NA	NA	
<b>Sex</b>	None identified	R&D administrative document	NA	NA	
<b>Sexual Orientation</b>	None identified	R&D administrative document	NA	NA	
<b>Carers</b>	None identified	R&D administrative document	NA	NA	

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	06/12/2017
R&D Committee	Royal Free London NHS Foundation Trust	25/01/2018

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