

## Document Title: Investigator Site File

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**Version Control**

<b>Version</b>	<b>Date</b>	<b>Author</b>	<b>Status</b>	<b>Comment</b>
1.0	01/07/2014	Eibhlin Geoghegan, Lead Research Nurse (Cancer)	Final	New SOP
1.1	03 OCT 2017	Lucy Parker	Final	SOP Review Date Time Extension
2.0	04 OCT 2017	Lucy Parker	Final	New SOP Template Addition of references to standard templates.

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## 1. INTRODUCTION

This Standard Operating Procedure (SOP) describes the process for maintaining the Investigator Site File for all research studies at RF.

## 2. OBJECTIVE

It is a legal requirement under the EU Clinical Trials Directive 2001/20/EC, EU Good Clinical Practice Directive 2005/28/EC and the Medicines for Human Use (Clinical Trials) Regulations 2004 for clinical trials to be conducted according to the principles of Good Clinical Practice (GCP). All studies should be run to GCP-equivalent standards to ensure consistent practice and scientific quality.

With the large volume of documentation required for each trial a standard filing system is necessary. Documentation for each study should be kept in an ISF (Investigator Site File) or TMF (Trial Master File) when the CI (Chief Investigator) is based at RF.

Some external Sponsors may provide the ISF for specific trials. The ISF provided by commercial companies should always be used for their particular trials. For other non-commercial but externally Sponsored trials either the ISF provided by the external body can be used or when the ISF has insufficient sections and a poor quality contents page, the Research Nurse (RN)/ Clinical Trial Practitioner (CTP), Data Manager (DM) responsible for that trial should set up a new ISF for that study where appropriate. The R&D Office has produced a template that can be used RFLRDDOC0003 ISF Non CTIMP Index.

## 3. SCOPE

The purpose of this SOP is to inform the Investigator and any nominated members of the research team on how to prepare and maintain an Investigator Site Filer file (ISF) throughout the lifetime of a study and to ensure that the filing system utilising the appropriate ISF index.

This SOP will not cover the preparation and maintenance of the TMF. Please refer to SOP 054 for that process.

## 4. DEFINITIONS

SOP	Standard Operating Procedure
GCP	Good Clinical Practice
RF	the Royal Free London NHS Foundation Trust
CI	Chief Investigator
DM	Data Manager
ISF	Investigator Site File
R&D	Research & Development
RF	Royal Free London NHS Foundation Trust
RN	Research Nurse
CTP	Clinical Trials Practitioner

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TMF Trial Master File

## 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 4.

## 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 Lead Research Nurse is responsible for oversight of this SOP.

Research Staff are delegated the development and upkeep of ISF by Sponsor. This person will undertake the duties to meet the responsibilities of the Sponsor in relation to the maintenance of all essential documents for the trial. Although there may be more than one member of the study team involved in updating the ISF, there should be one person who has overall responsibility for maintaining a particular ISF. Although this is delegated to the research staff, the PI at site remains ultimately responsible for the data that the site produced.

The Sponsor takes responsibility for the maintenance of all trial documentation produced prior to the clinical conduct of the trial, throughout the conduct of the trial and after the trial has ended according to the principles of ICH GCP. This task is usually delegated to the RN/CTP named in the Site Delegation/Participation Log.

### RF GCP Requirements

All Principal Investigators, Co-investigators, research staff working on regulated studies within RF are expected to undergo GCP training (Refer to SOP005 GCP Training) This should then be updated two yearly with issued training certificate filed in the staff members training folder and centrally

## 7. DETAILS OF THE PROCEDURE

Person Responsible	Task
PI	<p><b>7.1 Preparation of the ISF</b></p> <p>An ISF should be prepared as soon as possible after the first contact by the Sponsor or for trials where there is no external Sponsor, as soon as an outline protocol is available.</p> <p>It should be kept and maintained until the end of the trial, and archived thereafter in accordance with archiving agreements made at the beginning of the study or as agreed in the CTSA (Clinical Trial Site Agreement).</p> <p>There are some essential documents that must be kept by the Investigator and some/or both that are kept by the Sponsor, Appendix I outlines which documents must be retained and by whom. RFLRDDOC0003 ISF Non CTIMP Index (available on the RF intranet) outlines the contents page of a non CTIMP ISF when there is not one provided by the Sponsor, and can be used as a template in such situations. This document should also be used if setting up a RF Sponsored study.</p> <p>All essential documentation should be maintained in the ISF and updated as appropriate throughout the trial. The ISF will provide a central focus for monitoring either by telephone, email or visits and will be required to be available for all audits and inspections by the Sponsor or MHRA. Any essential documents not found should be requested from study Sponsor. If using RFLRDDOC0003 ISF Non CTIMP Index then it is suggested that the PI or a delegated member of their team regularly check the contents of the ISF are up to date by using RFLRDDOC0004 ISF Review Tool.</p> <p>As documents may be amended during the trial it is important that amendment chronologies are kept indicating the changes and the dates they are implemented. Old documents must be retained in the ISF alongside the new amended version (some trials provide a section in the ISF for superseded documents, or provide stickers to mark old documents as 'not for use') but should be clearly marked as superseded versions. (Refer to SOP003 Implementing Amendments for further information),</p> <p>If any of the essential documents cannot be stored in the ISF, e.g. CVs or old versions of the protocols, then a file note should be added to the ISF stating clearly where these documents can be found. A sample template is shown in appendix 3 and the R&amp;D Office has a standard ISF template that can be used for non CTIMP studies RFLRDDOC0003</p>

	<p>It is good practice to have a list of source (or a source SOP) to verify protocol compliance in the site file with a description of where source data can be found for monitoring, audit and inspection purposes.</p> <p>The list or SOP should also state what source demonstrates that each patient meets the inclusion/exclusion criteria and all key decision such as dose escalation decisions or meeting end of trial definition. The list of source data is primarily intended as a tool for monitors, auditors and inspectors in their work of verifying that the trial is performed in keeping with the ICH GCP guidelines, current legislation and guidelines as well as the trial protocol. Source data may be both electronic and on paper. The following list includes examples of where source data may be stored:</p> <ul style="list-style-type: none"> <li>• medical records</li> <li>• laboratory reports</li> <li>• diaries</li> </ul> <p>Where the site’s electronic patient records are deemed to be source, i.e. at the Royal Free hospital site, research staff should not print out source data from the electronic patient records for the purpose of monitoring, audit and inspection. Where the electronic patient records are deemed source, the monitors must perform source data verification (SDV) against the electronic record i.e. EDRM (see EDRM clinical trial guidance for access for monitors). This avoids gaps in the source data in the printed certified copies</p> <p>Documents should be filled in a consistent manner for all patients, to ensure accurate reconstruction of the trial.</p>
<p>PI</p>	<p><b>Storage and Archive</b></p> <p>All documents must be easily accessible and clearly labelled. The documents should be stored in an appropriate room before being moved to the authorised Archive facility. The room must be safe and secure with access only by authorised hospital appointed staff.</p> <p>In addition, refer to SOP044 Archiving, for details on the length of time files have to be stored for and the conditions for archiving of files.</p>

<p>PI</p>	<p><b>Which ISFs have to be archived?</b></p> <p>Trials where patients were screened and entered: ISF must be archived for the length of time stipulated in the archiving SOP or in the contract if it is stipulated.</p> <p>Trials where patients have signed a consent form and were screened but no one was entered: ISF must be archived for the length of time agreed in the CTSA (Clinical Trials Site Agreement) or the time stipulated in the archiving SOP.</p> <p>Trials where no patients signed a consent form and no patients were screened: Check with the Sponsor if it is permissible to discard the file contents in a confidential manner. If this is acceptable, then a list should be maintained of those trials of which the ISF has been discarded.</p> <p>Refer to Appendix 2 for a full listing of required essential documents and who is responsible for retaining them before the first patient is screened, during the trial and after completion or termination of the trial.</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**

RFLRDDOC0003 ISF Non CTIMP Index

RFLRDDOC0004 ISF Review Tool

## **11. FLOWCHART**

None applicable



**APPENDIX 2****Before the clinical phase of the trial starts**

<b>Topic</b>	<b>Located in Investigator Site File</b>	<b>Located in Trial Master File</b>
Investigator's Brochure	X	X
Signed protocol and amendments, if any, and sample case report form	X	X
Information given to trial subject Advertisement for subject recruitment	X	X
Financial aspects of the trial	X	X
Insurance statement (where required)	X	X
Signed agreement between involved parties	X	X
Dated, documented approval of Research Ethics Committee	X	X
HRA approval letter	X	X
Confirmation of Capability and Capacity	X	X
Regulatory Authority Authorisation (if applicable)	X	X
Curriculum vitae and other documents evidencing qualifications of investigator(s) and sub-investigator(s)	X	X
Normal values/ranges for medical/lab tests included in the protocol.	X	X
Medical/lab/technical procedures/tests Certification or accreditation; established quality control; other validation.	X	X
Sample of label(s) attached to medicinal products		X
Instructions for handling of investigational products and trial-related materials (if not in protocol or Investigator Brochure)	X	X
Shipping records for investigational numbers products		X
Certificates of analysis of investigational product shipped	X	X
Decoding procedures for blinded trials	X	X
Master Randomisation List		X
Pre-trial monitoring report		X
Trial initiation monitoring report	X	X

**During the clinical conduct of the trial**

<b>Topic</b>	<b>Located in Investigator site file</b>	<b>Located in trial master file</b>
Investigator's Brochure updates	X	X
Any revision to: <ul style="list-style-type: none"> <li>• Protocol/amendment(s) and CRF</li> <li>• Informed consent form</li> <li>• Patient/Parent Information Sheets</li> <li>• To document revisions of these documents during the course of the trial.</li> </ul>	X	X
Dated, documented approval of main ethical committee of the following: Protocol amendment(s) Revisions of: <ul style="list-style-type: none"> <li>• Informed consent form</li> <li>• Patient/Parent Information Sheets</li> <li>• Any other documents where approval required.</li> </ul>	X	X
Regulatory authorities approvals where required	X	X
Curriculum vitae for new investigator(s) and sub-investigator(s)	X	X
Updates to normal values/ranges	X	X
Updates of medical/lab/technical procedures/tests	X	X
Documentation of investigational product	X	X
Certificates of analysis for new batches of investigational product		X
Monitoring visit reports		X
Relevant communication other than site visits <ul style="list-style-type: none"> <li>• Letters inc. printed emails</li> <li>• Meeting reports</li> <li>• Notes of telephone calls</li> </ul> To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event reporting	X	X
Signed informed consent forms (originals)	X	
A file note * explaining where the source documents are located.	X	
Signed, dated and completed case report forms	X (copy)	X (original)
Notification by originating investigator to Sponsor of serious adverse events and related reports.	X	X
Notification by Sponsor and/or investigator, where applicable, to regulatory authorities of unexpected serious adverse drug reactions	X	X

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and of other safety information.	(where required)	
Notification by Sponsor to investigators of safety information	X	X
Interim or annual reports to main ethics committee	X	X (where required)
Subject screening log <ul style="list-style-type: none"> <li>To document identification of subjects who entered pre-trial screening.</li> </ul>	X	X (where required)
Subject identification log	X	
Subject enrolment log <ul style="list-style-type: none"> <li>To document chronological enrolment of subjects by trial number</li> <li>(The screening &amp; recruitment log can be combined into the one log)</li> </ul>	X	
Investigational products accountability at site <ul style="list-style-type: none"> <li>To document that investigational products have been used according to the protocol</li> </ul>	X	X
Site participants log <ul style="list-style-type: none"> <li>To document signatures and initials of all persons authorised to make entries and/or corrections on the CRFs.</li> </ul>	X	X
Record of retained body fluids/tissue samples (if applicable) <ul style="list-style-type: none"> <li>To document location and identification of retained samples if assays need to be repeated.</li> </ul>	X	X

### **After completion or termination of trial**

<b>Topic</b>	<b>Located in Investigator site file</b>	<b>Located in trial master file</b>
Investigational medicinal product(s) accountability at site	X	X
Documentation of investigational medicinal product destruction	X (if destroyed at site)	X
Completed subject identification log	X	
Audit certificate (if available) To document that audit was performed.		X
Final trial close-out monitoring report (if applicable) To document that all activities required for trial close out are completed, and copies of essential documents are		X

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held in appropriate files.		
Treatment allocation and decoding documentation		X
Final report by Chief Investigator to be sent to the main ethics committee. Principal Investigators to send to their R&D dept. where required To document completion of the trial	X	
Clinical study report To document results and interpretation of trial.	X (if applicable)	X

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**APPENDIX 3 example of an Example Site File (ISF) Index**

Essential documents required for Investigator Site File	Y	N	N/A	Comments
<b>1. PROTOCOL</b>				
Final approved protocol (signed copy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
All previously approved versions of protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol reviews	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol amendments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol references	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol drafts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Sub protocols	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>2. PATIENT INFORMATION</b>				
Patient Information Sheet(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Consent form(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
GP letter(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Diary card(s) / Patient card(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Signed consent forms				
<b>3. CASE REPORT FORM (CRF)</b>				
Final CRF	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
All previously approved versions of CRF	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CRF sign off sheet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Annotated CRF	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Instructions for CRF completion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CRF Amendments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>4. ETHICS</b>				
Ethics application(s)- submitted documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Ethics approval letter(s)- main and sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol amendments(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Annual Reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HRA approval letter ( and initial assessment letter)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>5. MHRA</b>				
CTA Application	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Approval letter(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol amendments:				
- Adding new clinicians/sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- Other amendments				
Inspection/ audit documentation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>6. CONTRACTS</b>				
Chief Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Sponsorship (including trial specific CTSA)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Insurance /Indemnity statement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pharmaceutical	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Laboratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
ARSAC				
<b>7. FUNDING AND FINANCE</b>				
Study budget	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Grant award letter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Payments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CLRN correspondance				
<b>8. LOCAL SITES</b>				
R&D submission	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Study checklist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
R&D approval letter (confirmation of capacity and capability)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Approval for amendments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other documentation (including ARSAC license)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Site correspondence (to include site specific CTSA/MTAs)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Document receipt faxes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Site set up data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Close out letter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Monitoring Reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Correspondences	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
File Notes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>9. SITE STAFF INFORMATION</b>				
Delegation logs (signed/dated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CV/ GCP certificates (dated/signed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Training including study training	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>10. LABORATORY</b>				
Certification/ accreditation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Samples documentation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>11. INVESTIGATIONAL MEDICINAL PRODUCT (IMP)</b>				
Site Pharmacy file	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Summary of arrangements for site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Ordering and shipping records	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Supplies accountability	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Sample labels	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Drug destruction records	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
QP Release	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Investigator Brochure (IB) or Summary Product Characteristics (SPC)- all versions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Supplies Process Flow Chart	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Certificates of analysis of shipped IMP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>12.RANDOMISATIONS/REGISTRATIONS</b>				
Randomisation/ registration file	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Enrolment/ randomisation list	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Unblinding procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
List of subjects (unblended)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Randomisation/ Registration procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Recruitment updates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Stratification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>13. PHARMACOVIGILANCE</b>				
SAE reporting guidelines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reports: SUSARs/ SAE log	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Annual safety reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Notifications of SUSARs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>14. PATIENT RECORDS</b>				
Copies of completed Case Report Forms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>15. Other</b>				

**APPENDIX 4**

**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	Investigator Site File
Briefly describe its aims and objectives:	To ensure that Site Files are maintained in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004
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
Is the Trust Equality Statement present?	<u>Yes</u> 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	R&D administrative document	NA	NA	This SOP on the preparation and maintenance of the investigator site file 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
<b>Disability</b>	None	R&D administrative document	NA	NA	
<b>Gender Reassignment</b>	None	R&D administrative document	NA	NA	
<b>Marriage and Civil Partnership</b>	None	R&D administrative document	NA	NA	
<b>Pregnancy and maternity</b>	None	R&D administrative document	NA	NA	
	None	R&D	NA	NA	

SOP 019: Investigator Site File

V2 04 OCT 2017

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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
<b>Race</b>		administrative document			Foundation Trust. 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	R&D administrative document	NA	NA	
<b>Sex</b>	None	R&D administrative document	NA	NA	
<b>Sexual Orientation</b>	None	R&D administrative document	NA	NA	
<b>Carers</b>	None	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 Development Group	Royal Free London NHS Foundation Trust	17.06.2014
R&D Committee	Royal Free London NHS Foundation Trust	24.06.2014