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Version Control

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1. INTRODUCTION

An essential element of conducting a clinical trial is efficient data collection and management. Only that data that is essential for the purposes of the study should be collected. It is advisable for investigators to seek advice from a trial statistician as early as possible in the trial design process to facilitate this.

ICH GCP Guidelines specify that appropriately qualified individuals should supervise the trial data handling, verify the data and conduct the statistical analyses (ICH GCP 5.5).

2. OBJECTIVE

This SOP describes the process for data management for RF Sponsored clinical studies. Specifically the processes involved with collecting, validating and analysing such data.

3. DEFINITIONS

RF Royal Free London NHS Foundation Trust

Independent Data Monitoring Committee - The role of the IDMC is to review interim study results and determine whether or not there are any safety issues or any reason why the study should not continue e.g. if interim results are showing strong evidence that the treatment/intervention is superior or inferior to the control.

Interim Analysis - An interrogation of intermediate results or study related data collected and evaluation based upon aims or objectives to be achieved during the course of the trial. The interim analysis may be predetermined at a specific time point of the study, e.g. after nn patients have completed 4 cycles of treatment.

Trial Steering Committee -The role of the TSC is to provide overall supervision for a trial on behalf of the Sponsor and Funder and to ensure that the trial is conducted to the rigorous standards set out in Good Clinical Practice. It does not handle the day to day management of the study. Its main focus is the progress of the trial, adherence to the protocol, patient safety and the consideration of any new relevant information.

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 that are relevant to the study.

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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.

TMF - The Trial Master File (TMF) contains all essential documents held by the sponsor/Chief Investigator which individually and collectively permits the evaluation of the conduct of a trial and the quality of the data produced.

ISF - The Investigator Site File (ISF) contains all essential documents held by Principal Investigator(s) conducting a trial which individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced.

CRF – Case Report Form (CRF) is a printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject. There is usually a case report form for each study visit, designed specifically to capture the information from that visit.

Essential documents - These are documents which permit evaluation of the conduct of the trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and the monitor with the standards of GCP and with regulatory requirements'

Source data - Source data is the "information in original records and certified copies of original records of clinical findings, observations, or any other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies)" [1]. All data that are collected for a clinical study must have a source to allow independent verification of the accuracy of the reported study (K Statutory Instrument, *Schedule 1, Part 2 (9)*).

4. SCOPE

This SOP describes the full data management process including: data entry; data cleaning; and resolving data queries. This SOP also describes the use of Data Monitoring Committees for assessing data during interim analyses, and how such a committee should operate.

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 should be read and understood by the Chief Investigator and all those in the research team that will be responsible for data management in order to understand their responsibilities in relation to the management of data during the lifecycle of the study.

7. PROCEDURE

Person Responsible	Task
PI/Research Team Member	<p>7.1 Source Data</p> <p>It is important to establish which documents will provide source data for the study. This will be study specific, and types of source documentation to be utilised should be detailed at the start of the trial. A source data list should be created to detail this; this may be within a study Standard Operating Procedure (SOP), Data Management Plan (DMP), or other document and file in the investigator site file for ease of monitoring.</p> <p>Good documentation of the source is required to ensure that the data and study results can be reconstructed, and can therefore be considered credible.</p> <p>Original principles of Good Documentation practice are described by the FDA using the acronym ALCOA: ‘attributable, legible, contemporaneous, original and accurate’</p> <p>Attributable: It should be clear who has documented the data.</p>

	<p>Legible: Readable and signatures identifiable in a form that is meaningful to an independent reviewer.</p> <p>Contemporaneous: The information should be documented in the correct time frame along with the flow of events. If a clinical observation cannot be entered when made, chronology should be recorded. Acceptable amount of delay should be defined and justified prior to trial recruitment [5].</p> <p>Original: The first record made by the appropriate person. If not original it should be exact copy. The investigator should have the original source document.</p> <p>Accurate: Accurate, consistent and real representation of facts.</p> <p>The EMA advise additional principles (and letters):</p> <p>Enduring: Long-lasting and durable.</p> <p>Available and accessible: Easily available for review of treating physicians and during audits/inspections. The documents should be retrievable in reasonable time.</p> <p>Complete: Complete to that point in time.</p> <p>Consistent: Demonstrate the required attributes consistently.</p> <p>Credible: Based on real and reliable facts.</p> <p>Corroborated: The data should be backed up by evidence.</p>
<p>Database Manager/ Trial Manager/Chief Investigator</p>	<p>7.2 Data Management Process</p> <p>The process of data management involves converting the source data collected using data collection tools, most commonly Case Report Forms (CRFs), into electronic data that can then be statistically analysed. This SOP will need to be read and utilised according to the size and complexity of the specific trial being conducted, as smaller trials may not require full use of the processes described.</p>
<p>Database Manager/ Trial Manager/Chief Investigator</p>	<p>7.3 Data Management Software</p> <p>Once the CRF has been designed in accordance with the protocol; the database to store the information collected should be designed. If an electronic data capture (EDC) system is used, it is important to ensure that the database has been validated and has been deemed fit for purpose through User Acceptance Testing (UAT). This process should be documented and saved within the Trial Master File.</p> <p>Depending on the size and type of study this database could be a standard spread sheet, or a more technical Data Management System may be required.</p> <p>When developing a database, points to consider include:</p>

	<ul style="list-style-type: none"> <input type="checkbox"/> ease of setting up and maintaining data entry screens; <input type="checkbox"/> the ability for more than one user to use the system at the same time; and <input type="checkbox"/> the ability to store and retrieve all data required for the study efficiently. <input type="checkbox"/> A full audit trail <p>The Sponsor or Chief Investigator (CI) should decide whether to have the database developed in-house or whether to purchase a system. If a decision is made to purchase a system for a RFL sponsored study, the CI must ensure that they speak with Procurement to ensure the system is fit for purpose. (Also see SOP014 contract negotiation and review). Further guidance on the use of trial data management systems can be provided by R&D's Data and Performance Analyst.</p> <p>Under ICH GCP the sponsor or delegate should produce a specific SOP for managing the study database in place. The database should allow changes to be made to the data in a documented manner, and should not delete the original data entry to ensure an audit trail for the data is maintained (ICH GCP 5.5.3).</p> <p>The database should be secure, with appropriate password-protected access to prevent unauthorised access to the data, with a list identifying those individuals permitted to make changes to the data. ICH GCP also requires that there is adequate backup for the data, and that if there is blinding involved in the study, that the data entry and processing systems allow this to be maintained (ICH GCP 5.5.3).</p> <p>For clinical trials involving Investigation Medicinal Products (CTIMPs) there must be an automatic electronically generated audit trail, rather than a handwritten log of database modifications. There are many electronic data capture systems (EDC) that can be purchased and modified to suit a particular study.</p>
<p>PI and research delivery team</p>	<p>7.4 Electronic data capture systems (EDC). All research staff delegated to enter data on to an EDC should log in to the EDC supplied by the sponsor prior to the study starting. Evidence of user access/logins should be captured in the sponsor's EDC audit trail.</p>

	Staff must not share passwords or usernames to EDCs.
PI and research delivery team	<p>7.5 EDC that are used for pharmacovigilance (reporting SAEs and SUSARs to sponsors)</p> <p>Where a sponsor is using the EDC for the site to record AEs, and/or report serious adverse events (SAEs) and SUSARs to the sponsor there should be evidence in the database that the PI, or delegated medic has logged in to review and approve before pharmacovigilance reports are submitted by RFL staff to the sponsor.</p> <p>The PI, or appropriate medical delegate, should log into the EDC and review SAEs in a timely manner.</p> <p>Non-medical staff must not, submit or ‘approve’ aspects of the EDC that require medical review i.e. reviewing SAE/SUSAR’s relatedness or causality, patient eligibility decisions. The sponsor EDC system would normally require a separate login for the PI or medic to enter and authorise medical decision within the EDC. There should be evidence that site staff have completed data that is appropriate to their delegated role.</p> <p>If the sponsor’s EDC does not have separate login for the PI or medic to authorise or submit AEs, SAEs or SUSARs</p> <p>The research team should complete the EDC as per sponsor SOPs and:</p> <ul style="list-style-type: none"> • Print off the relevant pharmacovigilance section of the EDC for the PI or delegated medic to wet-sign in a timely manner and save a copy in the site file as evidence of the RFL’s medical oversight. <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • Use a SAE proforma (hardcopy version of the E-SAE form) for the PI or delegated medic to wet-sign. The proforma should be version controlled and approved by the sponsor to ensure it captures all the required information for the IMP. The PI or delegated medic should sign the proforma in a timely manner and a copy should be saved in the site file as evidence RFL’s medical oversight.

	<p>See SOP 063 Safety Reporting for CTIMPs hosted by RFL</p>
<p>Database Manager/ Trial Manager/Chief Investigator</p>	<p>7.6 Coding CRF Responses</p> <p>Before data entry to the database, the responses from the CRFs must be coded, using either a numerical or alphabetical code that can then be used for analysis.</p> <p>These codes should be decided before data entry begins e.g. codes 0, 1 for Yes, No.</p> <p>Codes should also be in place for answers such as ‘not known’ or ‘not applicable’ e.g. 999 to show missing data. It is important to make sure that whatever value is chosen to represent missing data, that value would be unfeasible as an actual response, in order to prevent errors.</p> <p>Clinical data also needs to be coded for recording of all adverse events. The World Health Organisation Adverse Reaction Terminology (WHO-ART) and Medical Dictionary for Regulation Activities (MedDRA) both have a system of coding to assist with this categorised by System Organ Class. A code is assigned for each disease and adverse reaction. Investigators can access WHO-ART and MedDRA through http://bioportal.bioontology.org/ontologies/WHO-ART?p=classes&conceptid=root and www.medra.org respectively.</p> <p>The coding can be done at various stages of the trial such as: during the initial data collection from the participant by the investigator or research nurse; after the data collection, but prior to entering the data on the database; or after data has been entered onto the database.</p>
<p>Database Manager/ Trial Manager/Chief Investigator</p>	<p>7.7 Data Entry</p> <p>On initial receipt of CRF, the form should be date stamped and checked for initial missing or incomplete responses. If any inconsistencies are found these should be queried with the investigator and a record or log should be kept of all queries sent out. Instructions for sites to respond to data query responses should include no use of correction fluid, not to obscure the original data entry and to initial and date any amendments made.</p> <p>Once the paper CRFs have been completed, the data must then be entered onto the database. Data entry should be performed by trained data entry staff.</p>

	<p>For multicentre studies where the CRFs are being sent to a coordinating centre for data entry, a copy of the CRF should be retained by the Investigator, with the originals (usually 2 copies from NCR (No Carbon Required) Paper CRFs) going to the coordinating centre. If NCR is used, it should be checked to ensure readability. If in doubt, the NCR should be photocopied as the data recording will fade over time.</p> <p>The coordinating centre must keep a log of all CRFs received, maintained by the Data Manager for the study.</p> <p>All stored CRFs should be kept in a secure environment such as a locked filing cabinet in a locked room. Secure also means protection against environmental damage such as damp or fire, without water sprinklers.</p>
<p>Database Manager/ Trial Manager/Chief Investigator</p>	<p>7.8 Double and Single Data Entry with Control Checks</p> <p>During data entry by trained staff, an average error rate of 5% is expected. Two methods can be used to reduce the risk of errors: Double Data Entry or Single Data Entry with control checks.</p> <p>a. Double Data Entry This method involves two people entering the same CRF data onto the database independently of each other. Depending on the software used, the data may be entered twice onto the database on two separate files, which are then compared by the system for accuracy. If the two entries do not match this would be flagged up by the database.</p> <p>Alternatively when the second data entry person enters the data, if it differs from that entered by the first person, a message immediately appears on screen and the original data can be checked. This method depends on the availability of a technically capable database.</p> <p>b. Single Data Entry with Control Checks This method may be more suitable for smaller single centre studies with fewer staff available for data entry and/or less sophisticated database software. Once the data has been entered, a visual check can be done between what is recorded on the paper CRF, and what was entered on screen. One person should enter the data and a different person should do the visual check.</p>
<p>Database Manager/ Trial Manager/Chief</p>	<p>7.9 Data Cleaning and Validation</p>

<p>Investigator</p>	<p>An integral part of the data management process is validation; to ensure the most accurate 'clean' set of data is provided for the statistical analysis. Data validation can be carried out at three stages during the trial:</p> <p>a. When CRFs are completed by the investigator To improve accuracy at this stage all staff completing CRFs should be sufficiently trained in their completion. Validation should also be carried out as part of the ongoing monitoring of the study, either by members of the research team or by independent monitors</p> <p>Validation via monitoring is done through Source Data Verification (SDV). SDV involves checking the data entered into the CRFs against that in the original source records e.g. patient's hospital files for accuracy.</p> <p>The Trust's Electronic Data Records Management System (EDRM) is considered source data. Research staff should not print out copies from EDRM for the purposes of monitoring and auditing. Monitors/CRAs and auditors should complete their SDV against source i.e. EDRM. Any copies that are taken must be clearly labelled as certified copies of the source but should not be used for monitoring purposes.</p> <p>See R&D guidance document EDRM guidance for clinical trials' for the process of giving access to EDRM to CRAs and monitors.</p> <p>b. When data are entered in the database by data entry staff. During data entry the two methods for validation described above can be used e.g. single data entry. Where data entry checks are used, if the study database has software enabled for automatic data entry checks, an Edit Check Specification (ECS) document should be put together by the clinicians/statisticians/data staff involved with the study. The ECS should provide full details of the data entry checks that have been set up, and all checks should be tested before the trial begins. This is done by User Acceptance Testing (UAT).</p> <p>Depending on the database software, it is also advisable to set up warnings to alert data entry staff when values are entered outside of the expected range, or if the type of value entered is incorrect e.g. a numeric value entered rather than text. It is also useful to set up alerts for missing values where possible.</p> <p>c. When data have been entered and are available for</p>
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	<p>the data manager. At this stage it is advisable to carry out systematic post-entry computer tests. Lists should then be created (either through automatic database software system, or manually) of the following data queries:</p> <ul style="list-style-type: none"> . All missing values will be listed . All values outside of pre-defined range <p>Logical checks should also be performed to ensure consistent reporting between relevant fields and that there are no implausible differences between fields. All checks should be defined before the study starts, and should be described in the Edit Check Specification document described previously.</p> <p>Data validation should continue until all missing values and inconsistencies are corrected or clarified.</p>
<p>PI/Research Team Member</p>	<p>7.10 Documenting Study drug compliance (if applicable):</p> <p>RFL Clinical Trial Pharmacy SOPs outline the trust's process for documenting IMP accountability within pharmacy.</p> <p>Once the IMP leaves pharmacy the chain of custody and storage (if relevant to the trial protocol) of the IMP should be documented in the source data (medical notes) or in an IMP worksheet (usually provided by the sponsor). The site team should be able to demonstrate that the amount of IMP collected from pharmacy by the research team member was the same as that received by the participant.</p>
<p>PI/Research Team Member</p>	<p>7.11 Data Protection</p> <p>During the entire data management and validation process it is essential that all study data are kept in a secure location and in accordance with the terms of the Data Protection Act 1998 and subsequent regulations. Participant confidentiality must be maintained at all times and all study records should be kept in pseudonymised form identifying participants by their study code rather than name, initials or hospital number.</p> <p>Any paper CRFs should be kept in locked filing cabinets in locked rooms only accessible by authorised personnel. The key to the participant code list should be kept separately to these documents, again in a locked, secure location.</p> <p>If paper CRFs must be transferred to a coordinating centre for data entry, they should be sent either by</p>

	<p>courier or registered post to minimise the risk of losing data. A log should always be maintained of documents sent and received at each centre involved. If electronic data transfer is used, this should be via a secure system, password protected and encrypted where possible. At no stage, unless specifically consented to by the participant, should patient identifiable data be sent out of the originating NHS trust.</p> <p>The database itself should be password protected, with each data entry staff member having their own password. If data entry is performed at the investigator site it is essential that the investigator does not have access to the whole database, to protect against biases occurring due to investigators making decisions based on interim data.</p>
Database Manager/ Trial Manager/Chief Investigator	<p>7.12 Data Processing SOP</p> <p>Before the study starts, it is essential that a Standard Operating Procedure for data processing, management, and validation is put together, and updated as necessary through-out the study. The SOP should contain information on the following:</p> <ol style="list-style-type: none"> I. Contact details for all study staff II. Details of the flow of data from the investigator site to archiving III. Procedures on how to complete the CRFs IV. Monitoring plans e.g. frequency, how Source Data Verification will be done, V. Expected ranges for data values VI. Data Entry <ol style="list-style-type: none"> a. How to use the data entry system b. Double or single entry c. Roles and responsibilities of study staff with regard to data d. Procedures in case of discrepancies VII. Details of edit checks VIII. Description of Post Data Entry Validation System <ol style="list-style-type: none"> a. Who checks the consistency of the data? b. Who queries the Investigator? c. What is the format of the query form? d. How many days are allowed to answer a query? IX. Who decides that a query is resolved? X. Data Protection procedures, including a back-up system <p>Although the above list is not exhaustive it provides a basis for the Data Management SOP that can be adapted and expanded as necessary.</p>

Database Manager/ Trial Manager/Chief Investigator	<p>7.13 Data Backup Systems</p> <p>Whatever the format of the database software used to manage the study data, there should always be a back-up system in place to guard against loss of data due to software or environmental disasters. ICT may be able to advise whether the proposed backs up plans are fit for purpose.</p>
CI	<p>7.10 Independent Data Monitoring Committees (IDMCs)</p> <p>It is recommended for large, complex trials that an Independent Data Monitoring Committee (IDMC) is set up to carry out reviews of trial data at staged intervals during the study. The data reviewed by the monitoring committee should be, as up to date as possible and, should be validated up to the point of the interim analysis to ensure it is of sufficient quality. The membership of the committee should include experienced trial investigators, statisticians and clinicians; all of whom must be independent to the research team. The results should be reviewed at regular intervals as sufficient data accumulate. If there is a Trial Steering Committee (TSC) for the study, the IDMC would normally make their recommendations for action through them.</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

None applicable

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	Research Data
Briefly describe its aims and objectives:	This SOP describes the process for data management for RF Sponsored clinical studies. Specifically the processes involved with collecting, validating and analysing such data.
Directorate and Lead:	Rachel Fay, R&D Manager, R&D Office
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 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
Age	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.
Disability	None identified	R&D administrative document	NA	NA	
Gender Reassignment	None identified	R&D administrative document	NA	NA	
Marriage and Civil Partnership	None identified	R&D administrative document	NA	NA	
Pregnancy and maternity	None identified	R&D administrative document	NA	NA	
Race	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			
Religion or Belief	None identified	R&D administrative document	NA	NA	
Sex	None identified	R&D administrative document	NA	NA	
Sexual Orientation	None identified	R&D administrative document	NA	NA	
Carers	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	10/11/2017
R&D Committee	Royal Free London NHS Foundation Trust	21/12/2017