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This document supports: <i>Standards and legislation</i>	Medical Device Regulations 2002 Medical Device Directives 90/385/EEC and 93/42/EEC, ISO 14155:2011 (Clinical investigations of medical devices for human subjects – Good Clinical Practice) European Commission Guidelines on Medical Devices MEDDEV 2.7/3 UK Policy Framework for Health and Social Care (2017)
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Version Control

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Contents

Section		Page
1	Introduction	4
2	Objective	4
3	Definitions	4
4	Scope	7
5	Equality statement	7
6	Duties	7
7	Details of procedure	8
8	Policy	15
9	Risk management/liability/monitoring & audit	15
10	Forms/templates to be used	15
11	Flowcharts	16
Appendices		
Appendix (1)	SOP reading log	17
Appendix (2)	Equality analysis guide and tool	18

1. INTRODUCTION

It is essential that all adverse events or adverse device effects which occur during the course of study participants' involvement in a research project are appropriately recorded and reported in order to ensure their continuing safety. To ensure the interests and safety of subjects participating in clinical trials, this Standard Operating Procedure must be followed for all research studies that involve Investigational Medical Devices, as defined in the Medical Device Regulations 2002, Medical Device Directives 90/385/EEC and 93/42/EEC, ISO 14155:2011 (Clinical investigations of medical devices for human subjects – Good Clinical Practice).

The UK Policy Framework for Health and Social Care (2017) also lays out the requirement for safety reporting during a study.

2. OBJECTIVE

This document defines the Trust's requirements with regards to Adverse Event and Adverse Device Effect Reporting; specifically this includes Investigators and Researchers involved in any part of the research process that lies outside of the normal pathway of care.

It is essential that all Adverse Events (AE) and Adverse Device Effect (ADE) which occur during the participants' involvement in a research project are appropriately recorded and reported in order to ensure their continuing safety. Failure to report incidents, or deal with incidents adequately, can result in regulatory approval being withdrawn from an individual project, or, in extreme cases, from all research carried out by the Chief Investigator (CI) or Principal Investigator (PI).

The document aims to provide clear guidance on who takes overall responsibility for each process.

3. DEFINITIONS

Adverse Event (AE)

An adverse event (AE) is defined as any unfavourable and unintended sign including an abnormal laboratory finding, symptom or disease associated with the use of a medical intervention or procedure, regardless of whether it is considered related to the medical intervention or procedure, that occurs during the course of the study.

Serious Adverse Event (SAE)

Any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or in a congenital anomaly/birth defect. Important adverse events/reactions that are not immediately life threatening or do not result in death or hospitalisation, but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed above should also be considered serious.

Unexpected Related Serious Event

An Unexpected Related Serious Event is related to interventional studies with a procedure only. They are adverse events that are deemed serious, possibly related to the procedure and were not expected (as outlined in the protocol, manual or clinical practice). These should be reported to the Sponsor immediately. The Sponsor has an additional responsibility to report these to the REC within a set timeframe.

Adverse Device Effect (ADE)

An adverse device effect (ADE) is an adverse event that is deemed to be related to the use of an investigational medical device. This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the investigational medical device. An ADE includes any event that is a result of use error or intentional misuse. Use error refers to an act or omission of an act that results in a different device response than intended by the manufacturer or expected by the user. An unexpected physiological response of the subject does not in itself constitute a use error.

Serious Adverse Device Effect (SADE)

A SADE is an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

Anticipated Serious Adverse Device effect (ASADE)

A serious adverse device effect which by its nature, incidence, severity or outcome has been previously identified in the current version of the Clinical Investigation Plan (CIP), Risk Assessment or the Investigator's Brochure.

Unanticipated Serious Adverse Device Effect (USADE)

A serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the CIP, Risk Assessment and/or Investigator's Brochure.

Adverse Incident

Adverse incidents are events which affect the health and safety of patients or service users, equipment users or operators, or other persons. An Adverse Incident in relation to a medical device is an event that causes or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons. E.g. a patient, user, carer or professional is injured as a result of a medical device failure or its misuse, or if a patient's treatment is interrupted or compromised by a medical device failure or a misdiagnosis due to a medical device failure which leads to inappropriate treatment or a patient's health deteriorates due to medical device failure. Causes may include: design; poor user instructions or training; inappropriate modifications; inadequate maintenance; and unsuitable storage and use conditions.

Device Deficiency

Inadequacy of a medical device related to its identity, quality, durability, reliability, safety or performance, such as malfunction, misuse or use error and inadequate labelling.

Device Malfunction

Failure of an investigational medical device to perform in accordance with its intended purpose when used in accordance with the instructions for use or CIP.

Severity

The term "severe" is often used to describe the intensity (severity) of a specific event. This is not the same as "serious", which is based on patient/event outcome or action criteria. E.g. you can have a severe migraine; this would not constitute a serious adverse event.

Medical Device

A medical device is defined as any instrument, apparatus, appliance, material or other article, whether used alone or in combination with any software necessary for its proper application which is:

- a) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
- Diagnosis, prevention, monitoring, treatment or alleviation of disease
 - Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury
 - Investigation, replacement, modification, or support of the anatomy or of a physiological process
 - Supporting or sustaining life
 - Control of contraception
 - Disinfection of medical devices
- b) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

This definition of medical device is as per ISO 14155 Clinical investigation of medical devices for human subjects - Good Clinical Practice and does not apply to *in vitro* diagnostic medical devices (which is covered by ISO 13485:2003).

Investigational Medical Device

An Investigational Medical Device is a medical device being assessed for safety or performance in a clinical investigation. This includes medical devices already on the market that are being evaluated for new intended uses, new populations, new materials or design changes.

Clinical Investigation Plan (CIP)

A document that states the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record keeping of the clinical investigation.

Investigator's Brochure (IB)

A compilation of the current clinical and non-clinical information on the investigational medicinal device relevant to the clinical investigation.

Sponsor

An individual, company, institution or an organisation which takes on the responsibility for the initiation, management, and/or of the financing of a clinical trial.

Investigator

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator (PI).

Chief Investigator (CI)

An investigator assigned the overall responsibility for the trial including the coordination of participating principal investigators at participating sites within a multicentre trial.

RFL - Royal Free London NHS Foundation Trust

RM&G - Research Management & Governance

R&D - Research & Development

4. SCOPE

This SOP describes the process for recording, managing safety and reporting Adverse Events, Adverse Device Effects or Incidents for Royal Free sponsored Medical Device Studies or for Medical Device Studies hosted at a RFL site.

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 Chief Investigator (CI) has overall responsibility for the conduct of the study. In a multi-site study, the CI has co-ordinating responsibility for reporting adverse events to the Sponsor and to the relevant Research Ethics Committee (REC).

The Principal Investigator (PI) has responsibility for the research at a local site where the study involves specified procedures requiring site-specific assessment. There should be one PI for each research site. In the case of a single-site study, the CI and the PI should be the same person. The PI is responsible for informing the CI or the organising research team and the RFL R&D Office of all adverse events that occur at their site. The duties are summarised below:

- PI to report all SAEs/SADEs within agreed timelines, as per study protocol to the CI
- CI to report all SAEs/SADEs within agreed timelines to Sponsor and relevant NHS Trust R&D.
- CI to provide the Sponsor with details of all AEs/DEs identified in the protocol as critical to the evaluation of safety within the agreed timeframes specified in the protocol.
- CI to supply the Sponsor, REC and relevant NHS Trust R&D with any supplementary information they request.

The Sponsor's duties include:

- Promptly notifying all Investigators and REC(s) of any findings that may affect the health of subjects.

- To keep detailed written reports of all AEs/ADEs reported by PIs and performing an evaluation with respect to seriousness, causality and expectedness.
- Reporting all relevant safety information to the relevant REC.
- Ensure written SOPs and systems are in place to ensure quality standards and contractual agreements are met.

7. PROCEDURE

Person Responsible	Task						
CI/PI at site	<p>7.1 Assessment of Event or Effect</p> <p>All protocols should list known side effects; adverse reactions contained within the manufacturer’s product information or technical specifications and expected events in relation to the disease or population being studied that would not require expedited reporting. A detailed explanation of SAE/SADE reporting procedures should also be included in the protocol.</p> <p>The CI can decide how to record and report adverse events, whether expected or not. Adverse events must be recorded in the first instance in the participant medical notes. The Case Report Forms (CRFs) should also include event reporting where the event can be clearly described. It should be clearly stated in the study protocol and the local SOP what will be recorded and how the onward reporting and the ongoing participant management should be processed.</p> <p>The management and reporting arrangements for SAEs/SADEs should be in place for all trials. Agreements at the beginning of the trial should be made for such SAEs/SADEs that can be defined as disease-related and therefore not subject to expedited reporting. The procedures for managing and reporting SAEs/SADEs must be clearly defined in the protocol.</p> <p>As with all recording and reporting, subject confidentiality and adherence to the Data Protection Act (2018) must be maintained on all reports.</p> <p>Each AE/ADE must be evaluated for seriousness, causality, and expectedness. The responsibility for this evaluation can be shared between the CI and PIs. It may be most appropriate for the treating PI at each local site to evaluate whether each event is related and unexpected, before reporting it to the CI and Sponsor simultaneously. The definitions can be used below.</p> <table border="1" data-bbox="421 1727 1386 1944"> <thead> <tr> <th data-bbox="427 1736 703 1776">Relationship</th> <th data-bbox="710 1736 1380 1776">Relationship</th> </tr> </thead> <tbody> <tr> <td data-bbox="427 1785 703 1825">Unrelated</td> <td data-bbox="710 1785 1380 1825">There is no evidence of any causal relationship</td> </tr> <tr> <td data-bbox="427 1834 703 1935">Unlikely</td> <td data-bbox="710 1834 1380 1935">There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial medication). There is another reasonable explanation</td> </tr> </tbody> </table>	Relationship	Relationship	Unrelated	There is no evidence of any causal relationship	Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial medication). There is another reasonable explanation
Relationship	Relationship						
Unrelated	There is no evidence of any causal relationship						
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial medication). There is another reasonable explanation						

		for the event (e.g. the patient's clinical condition, other concomitant treatment).
Possible		There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial medication). However, the influence of other factors may have contributed to the event (e.g. the patient's clinical condition, other concomitant treatments).
Probable		There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely		There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out
Not assessable		There is insufficient or incomplete evidence to make a clinical judgement of the causal relationship.

AEs/ADEs that are not considered serious should be included in the patient notes and on the relevant case report forms (CRFs). The completed form should be filed along with the other CRFs for the study and a copy provided to the Sponsor as agreed.

The CI/PI at site must consult the current version of the IB and/or Risk Assessment to determine where an event is expected. Where applicable in blinded studies, unblinding must occur to assess treatment assignment.

SAEs/SADEs that are reportable are:

- **Related:** that is, it resulted from administration of any of the research procedures; and
- **Unexpected:** that is, the type of event is not listed in the protocol as an expected occurrence.

Adverse events and device effects that occur during the course of the Research project should be recorded collectively with the use of an AE & ADE log. The log should be maintained and retained in the Investigator Site File. The Sponsor may require regular collection or periodic updates of AE occurrence. All AE and ADEs must be observed to ensure that they do not escalate to an SAE/SADE.

If the event is classified as an anticipated effect, which by its nature, incidence severity or outcome has been previously identified in the Risk Assessment and/or IB and/or the Protocol. This event does not require reporting to the Sponsor or Regulatory Agencies but must be recorded in the medical records and RFLLRDLOG0019 AE & ADE log.

Where an event could be related to the medical device and is unanticipated in relation to the IB/ Risk Assessment, the Investigator must report this event immediately (within 24 hours) to the Sponsor/manufacturer and to the regulatory agencies within the required timelines.

CI	<p>7.2 Safety Reporting for Device Studies Sponsored by Royal Free – Event at a Royal Free Site</p> <p>A non-serious or unrelated adverse event does not need to be reported to the RLF R&D Office. All AE/ADE events that do occur during the course of the Research project should be recorded collectively e.g. RFLRDLOG0019 AE & ADE log - available to download from the website at www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/).</p> <p>If a research participant experiences a SAE or SADE, the CI should complete the SAE / ADE form (RFLRDDOC0012 - available to download from the website at www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/) and ensure the RFL R&D Office is informed within 24 hours of the CI becoming aware of the event, unless it is listed in the CIP as an expected event.</p> <p>It will be the CI's responsibility to forward the completed form to the relevant Ethics Committee and to the RFL R&D Office as Sponsor via email. The RFL R&D generic email mailbox should be included – rf.randd@nhs.net</p> <p>In the event that the CI/PI is unable to sign the report immediately, the research team/site should not delay sending the report, however a CI/PI signed copy must be forwarded to the RFL R&D Office as soon as possible (and within 7 days of the initial reporting). The research team/site must provide any additional information actively following-up the subject until either:</p> <ul style="list-style-type: none"> • The SAE/SADE/USADE resolves, or • Until 30 days after the discontinuation of use of the medical device <p>Reports of related and unexpected SAEs should be submitted to the REC that gave the favourable ethical opinion within 15 days of the CI becoming aware of the event.</p> <p>The REC will acknowledge receipt of the report within 30 days by signing the SAE form and returning a copy back to the person who made the submission.</p> <p>This signed copy will need to be retained in the appropriate section of the Investigator Site File.</p> <p>For all reportable events where there is an imminent risk or death, serious injury or serious illness and that requires prompt remedial action for other patients/subjects, users or other persons or a new finding to it: the CI/PI must report to the MHRA immediately, but no later than 2 calendar days after they become aware of such an event or new information in relation to an already reported event. This includes:</p> <ul style="list-style-type: none"> • Any SAE • Any device deficiency that might have led to a SAE if: <ul style="list-style-type: none"> ○ Suitable action had not been taken or ○ Intervention had not been made or ○ If circumstance had been less fortunate • New findings/updates in relation to already reported events
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	<p>Any other reportable events as outlined above or any new finding/update in relation to them must also be reported to the MHRA immediately, but no later than 7 calendar days after RFL R&D Office becomes aware of them. The CI/PI must notify the MHRA using the RFLRDDOC0054 MHRA Device Reporting Form. The Excel format gives a cumulative overview of the reportable events per clinical investigation and must be updated and transmitted to the MHRA every time a new reportable event or new finding to an already reported event is received.</p> <p>The PI/CI will need to update the status column of the tabular form as outlined below:</p> <p style="padding-left: 40px;">A = Added (new reportable event) M = Modified (new finding/update to an already reported event) U = Unchanged</p> <p>Changes in lines should be highlighted in bold and/or colour in the respective column.</p> <p>The report should be sent as an Excel file to aic@mhra.gsi.gov.uk quoting the MHRA's CI reference number or upload through MORE https://aic.mhra.gov.uk/ including the MHRA's CI reference number in the "incident description" field. All correspondence must be copied to the Sponsor.</p> <p>The letter of no objection from the MHRA will also detail whether summary reports (including their frequency) need to be submitted to the MHRA. The information to be submitted must be provided in tabular format as shown on the second tab of the MHRA Device Reporting Form.</p> <p>The letter of no objection will also detail whether protocol deviations must also be reported to the MHRA.</p> <p>Adverse events that occur during the course of the Research project should be recorded collectively e.g. RFLLRDLOG0019 AE & ADE log - available to download from the website at www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/).</p> <p>The log should be maintained and retained in the Investigator Site File. The RFL R&D Office as Sponsor may require regular collection or periodic updates of AE occurrence.</p> <p>The Investigator must also raise a DATIX incidence (see section 7.5)</p>
<p>PI at site</p>	<p>7.3 Safety Reporting for Device Studies Sponsored by Royal Free – Event at a non-Royal Free Site</p> <p>A non-serious or unrelated adverse event does not need to be reported to the RLF R&D Office. All AE/ADE events that do occur during the course of the Research project should be recorded collectively e.g. RFLLRDLOG0019 AE & ADE log - available to download from the website at www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/).</p> <p>If a research participant experiences a SAE or SADE, the PI at site</p>

	<p>should complete the SAE / ADE form (RFLRDDOC0012 - available to download from the website at www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/) and ensure the CI and RFL R&D Office is informed within 24 hours of the PI becoming aware of the event, unless it is listed in the CIP as an expected event.</p> <p>It will be the CI's responsibility to forward the completed form, from the PI, to the relevant Ethics Committee and to the RFL R&D Office as Sponsor via email. The RFL R&D generic email mailbox should be included – rf.randd@nhs.net</p> <p>In the event that the PI is unable to sign the report immediately, the research team at site should not delay sending the report, however a PI signed copy must be forwarded to the RFL R&D Office as soon as possible (and within 7 days of the initial reporting). The research team at site must provide any additional information actively following-up the subject until either:</p> <ul style="list-style-type: none"> • The SAE/SADE/USADE resolves, or • Until 30 days after the discontinuation of use of the medical device <p>Reports of related and unexpected SAEs should be submitted to the REC that gave the favourable ethical opinion within 15 days of the CI becoming aware of the event.</p> <p>The REC will acknowledge receipt of the report within 30 days by signing the SAE form and returning a copy back to the person who made the submission.</p> <p>This signed copy will need to be retained in the appropriate section of the Trial Master File and Investigator Site File.</p> <p>The REC will acknowledge receipt of the report within 30 days by signing the SAE form and returning a copy back to the person who made the submission.</p> <p>This signed copy will need to be retained in the appropriate section of the Investigator Site File.</p> <p>For all reportable events where there is an imminent risk or death, serious injury or serious illness and that requires prompt remedial action for other patients/subjects, users or other persons or a new finding to it: the PI must inform the CI immediately, but no later than 2 calendar days after they become aware of such an event or new information in relation to an already reported event. The CI will inform the MHRA immediately thereafter. This includes:</p> <ul style="list-style-type: none"> • Any SAE • Any device deficiency that might have led to a SAE if: <ul style="list-style-type: none"> o Suitable action had not been taken or o Intervention had not been made or o If circumstance had been less fortunate • New findings/updates in relation to already reported events <p>Any other reportable events as outlined above or any new</p>
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	<p>finding/update in relation to them must also be reported to the MHRA immediately, but no later than 7 calendar days after RFL R&D Office becomes aware of them.</p> <p>The CI must notify the MHRA using the RFLRDDOC0054 MHRA Device Reporting Form. The Excel format gives a cumulative overview of the reportable events per clinical investigation and must be updated and transmitted to the MHRA every time a new reportable event or new finding to an already reported event is received.</p> <p>The CI will need to update the status column of the tabular form as outlined below:</p> <ul style="list-style-type: none"> A = Added (new reportable event) M = Modified (new finding/update to an already reported event) U = Unchanged <p>Changes in lines should be highlighted in bold and/or colour in the respective column.</p> <p>The report should be sent as an Excel file to aic@mhra.gsi.gov.uk quoting the MHRA's CI reference number or upload through MORE https://aic.mhra.gov.uk/ including the MHRA's CI reference number in the "incident description" field. All correspondence must be copied to the Sponsor.</p> <p>The letter of no objection from the MHRA will also detail whether summary reports (including their frequency) need to be submitted to the MHRA. The information to be submitted must be provided in tabular format as shown on the second tab of the MHRA Device Reporting Form.</p> <p>The letter of no objection will also detail whether protocol deviations must also be reported to the MHRA.</p> <p>Adverse events that occur during the course of the Research project should be recorded collectively e.g. RFLLRDLOG0019 AE & ADE log - available to download from the website at www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/).</p> <p>The log should be maintained and retained in the Investigator Site File. The RFL R&D Office as Sponsor may require regular collection or periodic updates of AE occurrence.</p> <p>The Investigator at site must also inform the local R&D office of the SAE and follow their process of reporting at a local level e.g. through their Trust incidence reporting scheme.</p>
<p>Multi-Centre studies where duties have been delegated</p>	<p>7.4 Safety Reporting for Device Studies Sponsored by Royal Free – CTU Involvement</p> <p>All SAEs and SADEs from all sites must be sent to the RFL R&D Office unless alternative arrangements have been agreed.</p> <p>Where sites are managed through a third party contractor e.g. a Clinical Trials Unit it may be appropriate to make alternative arrangements for reporting. These arrangements will be specifically detailed in the Clinical Trial Agreement and/or Memorandum of</p>

	<p>Understanding.</p> <p>All SAE/SADE will be reviewed by the Director of R&D at the Quality Management Systems (QMS) Group meeting.</p> <p>Should a USADE be reported at any site, the RFL R&D Office will delegate the responsibility of informing all Principal Investigators involved in the study. Where required all medical devices at all sites will be quarantined until the MHRA investigation has been completed.</p>
<p>CI</p>	<p>7.5 DATIX Reporting</p> <p>You should also consider whether the event qualifies for reporting through the Trust's incidence system (DATIX). If the event requires a DATIX report, it can be accessed following this link:</p> <p>https://royalfree.datix.thirdparty.nhs.uk/Live/index.php</p> <p>The Adverse Incidents Reporting Policies and Procedures can be accessed following this link:</p> <p>http://freenet/freenetcms/Default.aspx?S=41&M=1859&P=1322</p>
<p>CI/ PI at Site</p>	<p>7.6 Quarantine of Devices</p> <p>The device should not be:</p> <ul style="list-style-type: none"> • Discarded • Repaired • Returned to the manufacturer • Removed from the site without previous agreement from the RFL R&D Office <p>The device must not be returned to the manufacturer until the MHRA has been given the opportunity to complete an investigation.</p> <p>All material evidence i.e. devices/parts removed, replaced or withdrawn from use following an incident, instructions for use, records of use, repair and maintenance records, packaging materials, or other means of batch identification must be:</p> <ul style="list-style-type: none"> • clearly identified and labelled • stored securely <p>Evidence should not be interfered with in any way except for safety reasons or to prevent its loss. Where appropriate, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with photographic evidence and eyewitness reports.</p> <p>Consideration should be given to the practicality and implications of quarantining the device; for example if the device is an implantable device, all further supplies of the device should be quarantined as a precaution until further advice is sought.</p> <p>The CI and RFL R&D Office will undertake any requirements outlined in the MHRA investigation and follow-up as instructed.</p>

Assigned Research Portfolio Manager	<p>7.7 Handling of SAEs</p> <p>The Assigned Research Portfolio Manager will work with the CI/PI to ensure that the SAE form is completed correctly and that the CI/PI sends the form to the REC within the stipulated timelines.</p> <p>The Assigned RPM will save a copy of the SAE form in the safety reporting section of the study record folder on the R&D study database.</p> <p>All SAE/SADE/USADE reported to the RFL R&D Office will be discussed and reviewed at the QMS Meeting by the Director of R&D. This review may lead to queries being issued by the RFL R&D Office to request signed documentation, clarify information or complete event outcome.</p>
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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

RFLRDDOC0012	-	Safety Report Form Non-CTIMP
RFLRDDOC0054	-	MHRA Device Reporting Form
RFLRDLOG0019	-	AE & ADE Log

11. FLOWCHART

None applicable

APPENDIX 1
SOP Reading Log

READ BY			
NAME	TITLE	SIGNATURE	DATE

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	Safety Reporting for non CTIMP studies
Briefly describe its aims and objectives:	To define the Trust’s requirements with regards to Adverse Event Reporting specifically this includes Investigators and Researchers involved in any part of the research process that lies outside of the normal pathway of care.
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	

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, and 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	
R&D Committee	Royal Free London NHS Foundation Trust	