

Document Title: Annual Progress Reports (APRs)

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Version Control

Version	Date	Author	Status	Comment
1	19 SEPT 2017	Lucy Parker	Final	New document
1.1	19 Oct 2018	Neil Hubbard	Final	Update from ReDA to EDGE Database. Removal or references to SOP Working group and replacing with QMS Working Group. Deletion of Reading log.

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1. INTRODUCTION

NHS Research Ethics Committees (RECs) are required to monitor research that has received a favourable opinion. A progress report should be submitted to the REC which gave the favourable opinion 12 months after the date on which the favourable opinion was given. Annual progress reports should be submitted annually thereafter until the end of the study. An electronic copy should be emailed to the REC within 30 days of the end of the reporting period

2. OBJECTIVE

The purpose of this SOP is to detail the process for the preparation, and submission of Annual Progress Reports for studies sponsored by Royal Free London.

3. DEFINITIONS

REC the Research Ethics Committee (REC) which gave the favourable opinion

RF Royal Free London NHS Foundation Trust

4. SCOPE

This SOP will describe the process for the preparation, and submission of Annual Progress Reports for studies sponsored by Royal Free.

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.

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This SOP is to be followed by the RF R&D Office and the Chief Investigator (CI) of the proposed study.

It is the responsibility of the R&D Manager to ensure that this SOP is updated by the review date or as necessary.

It is the responsibility of the CI to ensure that they have read and understood the RF R&D Office SOPs and ensured that their team familiarise themselves with the SOPs. It is also their responsibility to ensure that they check that they are working with the most current version of the SOPs

The CI is responsible for providing a copy of the Annual Progress Report (APR) and a copy of the REC acknowledgement upon receipt to the Research Portfolio Manager.

The CI must also ensure a copy of the APR is filed in the TMF

The Research Portfolio Manager will ensure a copy of the APR is filed in the electronic study folder located on EDGE.

It is important to ensure that an APR exists that covers the entire study. So for example, if a study only lasts 9 months, that an APR is sent in covering the 9 months in question.

7. PROCEDURE

Person Responsible	Task
CI	<p>The First Annual Progress Report</p> <p>The first annual progress report should be submitted to the REC 12 months after the date on which the favourable opinion was given.</p> <p>The template can be found on the HRA website. Please ensure you use the correct template. www.hra.nhs.uk/resources/during-and-after-your-study/nhs-rec-annual-progress-report-forms</p> <p>The CI is advised to visit the HRA website to ensure they have the correct email contact and the correct address location of the REC that originally approved the study.</p> <p>The APR should state the commencement date for the study. This is normally assumed to be the date on which any of the procedures in the protocol are initiated.</p> <p>If the study has not started within 12 months of the favourable opinion, an explanation for the delay in the first progress report must be given.</p>

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	<p>Copies of the APR must be sent to the Sponsor, the PIs at all sites and the R&D offices of all active sites. This allows them to know that the study is still active and is often a condition of Trust approval.</p>
CI	<p>Annual Progress Reports (Year 2 onwards) Progress reports should be submitted annually thereafter until the end of the study.</p> <p>The REC may exceptionally request more frequent reports.</p> <p>Alternatively, following receipt of the first progress report, the chair of the REC has the discretion to waive the requirement for further reports on receipt of a written request from the Chief Investigator. This might be appropriate where a study has completed recruitment and intervention but has a long period of follow-up with minimal participant involvement.</p> <p>Ensure a copy of this waiver is forwarded to the R&D Office Research Portfolio Manager to facilitate update of the EDGE database.</p> <p>Copies of the APR must be sent to the Sponsor, the PIs at all sites and the R&D offices of all active sites. This allows them to know that the study is still active and is often a condition of Trust approval.</p>
CI	<p>Multi-Site Studies In the case of multi-site studies, only one progress report needs to be submitted to the REC. This will usually be done by the Chief Investigator. Once REC has acknowledged the APR, the CI is responsible for forwarding this report on to all other participating sites.</p>
Research Portfolio Manager	<p>Acknowledgment and Filing of APR The Research Portfolio Manager will ensure a copy of the APR is filed in the electronic study folder located on EDGE and acknowledge receipt of the APR via email to the CI.</p>

8. POLICY

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

9. RISK MANAGEMENT/ LIABILITY/MONITORING & AUDIT

- The QMS 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).

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- 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 used.

11.0 FLOWCHART

None applicable

APPENDIX 1

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APPENDIX 2

Royal Free London NHS Foundation Trust Equality Analysis guide and Tool

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

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

Name of the policy / function / service development being assessed	SOP on Annual Progress Reports
Briefly describe its aims and objectives:	This SOP will describe the process for the preparation, and submission of Annual Progress Reports for studies sponsored by Royal Free
Directorate and Lead:	Rachel Fay, R&D Manager
Evidence sources: DH, legislation. JSNA, audits, patient and staff feedback	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care (2017)
Is the Trust Equality Statement present?	Yes X No if no do not proceed with Equality Analysis (EA)

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

Equality Analysis Checklist

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

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

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

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Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
Religion or Belief	None identified	R&D administrative document	N/A	N/A	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.
Sex	None identified	R&D administrative document	N/A	N/A	
Sexual Orientation	None identified	R&D administrative document	N/A	N/A	
Carers	None identified	R&D administrative document	N/A	N/A	

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

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

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