STANDARD OPERATING PROCEDURE: Generating and Submitting REC Annual Progress Reports

SOP REFERENCE NUMBER:	CLPG19 SOP 8
VERSION NUMBER:	1
REPLACES SEPT DOCUMENT	SOP 14 - Generating and Submitting REC Annual Progress Reports
REPLACES NEP DOCUMENT	N/A
KEY CHANGES FROM PREVIOUS VERSION	Updated for EPUT
AUTHOR	Research and Development Manager
CONSULTATION GROUPS	
IMPLEMENTATION DATE	
AMENDMENT DATE(S)	
LAST REVIEW DATE	
NEXT REVIEW DATE	
APPROVAL BY CLINICAL GOVERNANCE & QUALITY SUB-COMMITTEE	March 2018
RATIFICATION BY QUALITY COMMITTEE	April 2018
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SOP SUMMARY

This SOP outlines the procedure for the preparation and submission of Research Ethics Committee (REC) Annual Progress Reports.

The Trust monitors the implementation of and compliance with this policy in the following ways;

Monitoring of implementation and compliance with this procedure will be undertaken by the Executive Medical Director, Research manager, Research lead, R&D department staff and R&D group.

Services	Applicable	Comments
Trustwide	✓	
Essex MH&LD		
CHS		

ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

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CONTENTS

1. BACKGROUND

It is a legal requirement under The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) regulation 35 that the Sponsor of a clinical trial of an investigational medicinal product (CTIMP) must provide the competent authority (CA) (Medicines and Healthcare Products Regulatory Agency (MHRA)) with and Annual Safety Report **and** the Research Ethics Committee (REC) with an Annual Progress Report (APR) for every study they sponsor.

For non-CTIMP studies only, an Annual Progress Report needs to be submitted to the REC to maintain the RECs favourable opinion. Annual progress reports should be submitted thereafter until the end of the study.

For studies with HRA Approval which were not required to be reviewed by a REC, progress reports should be sent to hra.approval@nhs.net

2. PURPOSE

This Standard Operating Procedure (SOP) describes procedures for the preparation and submission of REC Annual Progress Reports (APRs) for Essex Partnership University NHS Foundation Trust (EPUT) non-CTIMP sponsored studies. This task of generating and submitting APRs to REC is typically delegated to the Chief Investigator (CI).

3. APPLICABLE TO

This SOP is applicable to all EPUT CIs.

4. PROCEDURE

The CI is to generate and submit the APR to the appropriate REC **prior** to the anniversary of obtaining the REC favourable opinion and forward a copy to the Research department. The relevant forms are available from the HRA website: http://www.hra.nhs.uk/research-community/during-your-research-project/progress-reporting/

5. SUPPORTING DOCUMENTS

None

6. REFERENCES

The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) regulation 35

Health Research Authority

Medicines and Healthcare Products Regulatory Agency

7. APPENDICES

None