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SOP 14 - Generating and Submitting REC Annual Progress Reports  
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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.  

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<td>CHS</td>
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</tr>
</tbody>
</table>
STANDARD OPERATING PROCEDURE:
Generating and Submitting REC Annual Progress Reports

CONTENTS

1. BACKGROUND
2. PURPOSE
3. APPLICABLE TO
4. PROCEDURE
5. SUPPORTING DOCUMENTS
6. REFERENCES
7. APPENDICES
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