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<h1>Annual Progress Report</h1>	
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Version 1.0	25 Oct 2017	1 st Edition
Version 2.0	01 Feb 2019	Office change from Research Governance and Integrity Team to Research Governance and Integrity Team
Version 3.0	06 Oct 2020	Scheduled Review Templates removed and administrative changes to SOP.
Version 4.0	25 March 2021	Update to APR requirements for study duration and proportionate review

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1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for preparing and submitting Annual Progress Reports (APR) to the Research Ethics Committee (REC) for all research projects sponsored by Imperial College London and Imperial College Healthcare NHS Trust.

2. INTRODUCTION

The Medicines for Human Use (Clinical Trial) Regulations (2004) and the Health Research Authority (HRA) state that for all clinical trials of Investigational Medicinal Products (CTIMPs), and for all other clinical research (non-CTIMPs), an annual progress report of the study should be submitted on the anniversary of the Research Ethics Committee (REC) favourable opinion of the research protocol. This is only required for studies that have an expected duration of more than 2 years, and studies which were reviewed at a full REC meeting. Studies that undergo proportionate review are not required to submit APRs.

Research Ethics Committees are required to keep a favourable opinion under review in the light of progress reports and any developments in the trial. The APR shall be submitted regardless of whether or not recruitment has started. If recruitment has not started, an explanation should be included in the APR.

Progress reports should be in the format prescribed by the REC, published on the [HRA website](#) (Cited 11 May 2020).

Reports may be submitted by the sponsor or the Chief Investigator (CI) but should always be signed by the CI. For all Imperial College London and Imperial College Healthcare NHS Trust sponsored research, the task is delegated to the CI.

3. PROCEDURE FOR SUBMISSION OF ANNUAL PROGRESS REPORT FOR CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS (CTIMPs)

Lines and method of communication

It is the responsibility of the Chief Investigator (CI), or someone delegated by the CI, to provide an annual progress report to the following:

- i) the Sponsor - for Imperial College Academic Health Science Centre (AHSC) studies, this is the Research Governance and Integrity Team (RGIT); The CI or its delegate shall forward the draft APR to the RGIT for review at least 2 weeks prior to the required submission date.
- ii) the Research Ethics Committee (REC) which gave a favourable opinion of the research (the 'main REC'); Submission should be made via email.
- iii) The CI/delegate must ensure that a copy of the APR, acknowledgement and any other communication with the REC, Sponsor or R&D are filed within the TMF.

The NHS Research Ethics Committee Annual Progress Report form [HRA website](#) (Cited 11 May 2020) must be completed in typescript and must be signed by the CI.

The Committee should be kept informed of any significant findings or recommendations by an independent Data Monitoring Committee or equivalent body established for the trial.

4. PROCEDURE FOR SUBMISSION OF ANNUAL PROGRESS REPORT FOR ALL OTHER CLINICAL RESEARCH (non-CTIMPs)

Lines and method of communication

It is the responsibility of the Chief Investigator (CI), or someone delegated by the CI, to provide an annual progress report to the following:

- i) the Sponsor - for Imperial College Academic Health Science Centre (AHSC) studies, this is the Research Governance and Integrity Team (RGIT). The CI or its delegate shall forward the draft APR to the RGIT for review at least 2 weeks prior to the required submission date. Submission should be made via email.
- ii) the Research Ethics Committee (REC) which gave a favourable opinion of the research (the 'main REC');

The NHS Research Ethics Committee Annual Progress Report form [HRA website](#) (Cited 11 May 2020) must be completed in typescript and must be signed by the CI.

Research Database Annual Report to REC please see – [HRA website](#) (Cited 11 May 2020)

For Research Tissue Bank/Biobank – Annual Report to REC please see – [HRA website](#) (Cited 11 May 2020)

5. TIMING OF NOTIFICATION

The Chief Investigator should submit a progress report to the Research Ethics Committee 12 months after the date on which the favourable opinion was given. Annual progress reports should be submitted 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.

6. REFERENCES

[Clinical Trials Toolkit](#) (Cited 11 May 2020)

[Health Research Authority NHS UK](#) (Cited 08 Aug 2020)

[HRA annual progress report forms](#) (Cited 11 May 2020)

[Research Ethics Committee – Standard Operating Procedures](#) (Cited 11 May 2020)