# SOP05 - Study Monitoring and Annual Reports

1. **Introduction and Scope**

This SOP details the procedures for managing the submission of Annual Progress Reports (APRs) for research studies sponsored by DMU. This SOP applies to all research where DMU acts as sponsor in accordance with the UK Policy Framework for Health and Social Care.

1. **Study Commencement**

The Research Governance Office should be notified upon recruitment of the first participant. This is so the RGO are aware that the study has commenced.

The HRA expect that once approved, research should normally commence within 12 months of the date on which a favourable ethical opinion is given by a REC. In the event that research has not commenced, a report must be submitted to the REC in line with the HRA SOPs.

1. **Annual Reporting**

It is a condition of DMU ethics approval and Research Ethics Committee (REC) Favourable Opinion that progress reports will be submitted.

Annual reports should then be submitted to the Research Governance Office 11 months after REC approval has been granted and on the same date in subsequent years.

For studies that are greater than two years in duration, and were not approved by proportionate review, after submission within DMU authorisation will be granted for submission to the approving REC. The Chief Investigator must complete the relevant Annual Progress Report form (APR) and submit it to the Research Governance Office for review and authorisation prior to submission to the REC.

The Research Governance Office will alert the Chief Investigator at least one month before the APR is due to be submitted. A reminder email will be sent every four weeks after the due date for up to three occasions (3 months) after which failure to submit will result in the non-compliance being implemented, with action being taken at a Critical level.

The completed APR must be retained in the Trial Master File along with any acknowledgement correspondence received from the REC, NHS Trust R&D Offices and the Sponsor.

Template forms can be accessed on the Health Research Authority website: <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/>

Non-CTIMPs: Any serious adverse events (SAEs) must be included as a Line Listing for the whole study, including information from all sites.

1. **Monitoring by Faculty of Health and Life Science Research Ethics Committee**

APRs will be reported at the next available HLS FREC, at which members will have the opportunity to comment on progress and the continuation of research activities. Significant concerns relating to a study may results in escalation to the University Research Ethics Committee or a decision to place the study on hold.

As appropriate, audits of research may be completed on behalf of, and reported to the HLS FREC to evidence compliance against DMU SOPs, study protocols and regulatory and ethics approvals. Audits will normally be facilitated by the Research Governance Office, and it is expected that each study will receive an audit during the lifetime of its duration.

1. **Document Control**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT** | | | | | | |
| **Author:** Douglas Gray | | | | | **Job Title:** Faculty Head of Research Ethics (HLS) | |
| **Approved by:** University Research Ethics Committee | | | | | **Date Approved:** 14/04/2021 | |
| **REVIEW RECORD** | | | | | | |
| **Date** | **Issue**  **Number** | | **Reviewed By** | **Description of Changes (If Any)** | | |
|  |  | |  |  | | |
|  |  | |  |  | | |
|  |  | |  |  | | |
| **DISTRIBUTION RECORD:** | | | | | | |
| **Date** | | **Name** | | **Dept** | | **Received** |
|  | |  | |  | |  |
|  | |  | |  | |  |
|  | |  | |  | |  |
|  | |  | |  | |  |