



Standard Operating Procedure Research Governance

Title:	Production of Progress Reports		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

1 Purpose

This Standard Operating Procedure (SOP) describes the process for the production and submission of annual progress and final reports to the Research Ethics Committee (REC) and the University.

2 Procedure

The responsibility for submitting the progress report is delegated to the Chief Investigator (CI). For studies with NHS/HSC REC approval a copy of any correspondence to the REC should be sent by email to the Research Governance team, as study sponsor (researchgovernance@qub.ac.uk).

2.1 Progress Report

2.1.1 Studies with NHS/HSC REC Approval

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. Progress Reports are only required for studies that are more than two years in duration and for Research Tissue Bank and Research Databases. There is no requirement for a Progress Report for Proportionate Review studies and where the study is two years or less in duration.

There are separate forms for submitting progress reports, depending on the type of research. These are available from the HRA website: <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/>.

The forms should be completed in typescript. They will need to be authorised by the Chief Investigator or the sponsor/sponsor representative.

An electronic copy should be emailed to the REC within 30 days of the end of the reporting period.

The first annual progress report should state the date that the study commenced. Commencement of a study is considered to be when any of the procedures set out in the protocol are initiated. It is expected that a study will normally begin within 12 months of the date on which the REC gave the favourable ethical approval of the research.

If there is a delay in the commencement of the study, and it does not begin within 12 months, the CI should give the REC a written explanation for the delay in the first annual progress report.

Should there be a further delay, and the study does not commence within 24 months, a further explanation should be given. If this is the case, the REC may decide to review its opinion.

In the event that a study has a long period of follow-up with minimal participant involvement, the CI may make a written request to the Chair of the REC to request the requirement of an annual progress report be waived.

If a study is abandoned before beginning, the CI should notify the REC by letter, giving reasons. It is not necessary to submit the form for declaring the conclusion or early termination of the study. If a study is abandoned and it is later proposed to start it afresh, a new application should be made.

2.1.2 Studies with HRA and HCRW Approval only

For research with HRA and HCRW Approval which were not required to be reviewed by a REC, progress reports are not required.

These requirements apply to all research with HRA and HCRW Approval.

2.1.3 Confidentiality Advisory Group (CAG) annual review

Where a project has required CAG approval, there is a need for the approval to be reviewed on an annual basis to assess the need for continuing approval and to ensure that progress towards, or achievement of, any conditions of approval is in place. An annual review report should be submitted to the Confidentiality Advice Team by email four weeks before the approval expires (i.e. no later than 11 months following the final approval date) using a specified report template. This is available from the HRA website. The annual review report will be assessed by the [Confidentiality Advice Team](#) in the first instance.

A copy of any correspondence to the CAG should be sent by email to the Research Governance team, as study sponsor (researchgovernance@qub.ac.uk).

2.1.4 Studies with Queen's University Belfast Faculty REC Approval

Where a study has ethical approval from one of the University's Faculty REC, the Chief Investigator should submit an Annual Progress Report form to the relevant Faculty REC by email 12 months after the original ethical approval date. The report will be acknowledged by the Research Ethics Officer and noted by the Faculty REC.

3. References

UK Health Departments Standard Operating Procedures for Research Ethics Committees, version 7.5.1, August 2021 (last accessed September 2021):
https://www.hra.nhs.uk/documents/2490/RES_Standard_Operating_Procedures_Version_7.5.1_August_2021_Final_Accessible_071VkJt.pdf

HRA Progress Report Forms (last accessed September 2021):
<https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/>

QUB Faculty REC Progress Report Forms (last accessed September 2021):
<https://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Ethics/FacultyResearchEthicsCommittees/>