STANDARD OPERATING PROCEDURE FOR PREPARING AND SUBMITTING PROGRESS REPORTS FOR RESEARCH STUDIES

SOP NUMBER:	**Fife R&D SOP08**
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1. PURPOSE

This document describes the procedure for preparing and submitting Annual Progress Reports for research studies which are sponsored or co-sponsored by NHS Fife.

It is the responsibility of all staff using this SOP to ensure they are using the latest version of it. The latest version is available via StaffLink, the R&D section of the NHS Fife website (www.nhsfife.org/research) and EDGE (https://www.edge.nhs.uk). For guidance, contact the R&D Department via fife.randd@nhs.scot

2. APPLICABILITY

This SOP applies to any individual involved in the preparation and submission of Annual Progress Reports for research studies which are sponsored or co-sponsored by NHS Fife.

3. POLICY

3.1 Research Ethics Committees are required to monitor research that has received a favourable opinion. Therefore, researchers must submit Annual Progress Reports in order to inform the REC of the progress of the research. The information required in an Annual Progress Report relates to research conduct, recruitment, amendments, and safety.

3.2 It is the responsibility of the Chief Investigator (CI) to ensure all Annual Progress Reports are prepared and submitted to the Research Ethics Committee (REC) that gave the original favourable opinion for the study and to all NHS R&D Offices responsible for care organisations in which the research is conducted.

4. PROCEDURE

4.1 ANNUAL PROGRESS REPORT

4.1.1 The format of the Annual Progress Report will depend on the type of research being conducted. The appropriate form must be selected from the templates available from the Health Research Authority (HRA) website: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/

4.1.2 Annual Progress Reports must be submitted annually, with the first report submitted 12 months after the date of the favourable opinion. Annual Progress Reports must be submitted annually thereafter until the end of the study. The report should be submitted on or prior to the anniversary of the first REC approval plus 30 days.

4.1.3 If the study has not started within 12 months of the favourable opinion, an Annual Progress Report must be submitted with an explanation for the delay.

4.1.4 An electronic copy of the report must be emailed to the REC within 30 days of the end of the reporting period and a copy also sent to the NHS Fife R&D Approvals Team (fife.fiferesearchapprovals@nhs.scot).

4.1.5 The person submitting the report must request an acknowledgement of its receipt from the REC to whom it is submitted.

4.1.6 A copy of the Annual Progress Report plus all correspondence must be filed in the Sponsor File and Study Master File.

4.1.7 Following receipt of the first Annual Progress Report, the chair of the REC has the discretion to waive the requirement for further reports on receipt of a written request from the CI. This might be appropriate where a study has completed recruitment and intervention but has a long period of follow-up with minimal participant involvement.

4.2 END OF STUDY REPORT

4.2.1 The CI must send a summary of the final research report to the REC within 12 months of the end of the study as defined in the protocol. The recommended definition of end of study date is 'last participant, last visit' but this may be changed if appropriate e.g., study database lock (see R&D SOP33).

4.2.2 There is no standard format for the final report. As a minimum, the CI must inform the REC whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research, including any feedback to participants.

For further guidance on the format of the report see the HRA website: http://www.hra.nhs.uk/research-community/end-of-study-and-beyond/notifying-the-end-of-study/.

4.2.3 The final report must be emailed to the REC and a copy also sent to the NHS Fife R&D Approvals Team (fife.fiferesearchapprovals@nhs.scot).

5. ASSOCIATED DOCUMENTS

R&D SOP33 – Closure of Clinical Research Studies

Annual Progress Report Form Templates
HRA website - https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/..

6. ABREVIATIONS

CI Chief Investigator
HRA Health Research Authority
REC Research Ethics Committee
R&D Research and Development
SOP Standard Operating Procedure

7. REFERENCES

Annual Progress Report Forms
HRA website: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/..

Ending your Project:
HRA website: http://www.hra.nhs.uk/research-community/end-of-study-and-beyond/notifying-the-end-of-study/

8. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of editions made:
1	Julie Aitken R&D Trials Facilitator	02/02/2015	New - adapted from TASC SOP 15, Version 5
2	David Chinn	10/06/2015	Review from Tayside - addition of reporting timeline for REC annual progress report.
3	Julie Aitken R&D Trials Facilitator	10/05/2018	Minor changes to reflect current practice and clarify procedure.
4	Julie Aitken R&D Quality & Performance Lead	10/06/2020	Reformatted in line with current SOP template. Reference to CTIMPs and DSUR removed as NHS Fife does not Sponsor CTIMPs.
5	Julie Aitken R&D Quality & Performance Lead	31/10/2023	Minor changes to text and formatting only

9. APPROVAL

APPROVED BY	Date
Professor Frances Quirk, Assistant Director RIK, NHS Fife Signature: 	31 Oct 2023