STANDARD OPERATING PROCEDURE FOR PREPARING AND SUBMITTING ANNUAL PROGRESS REPORTS FOR CLINICAL RESEARCH

SOP NUMBER:	TASC SOP015 v12
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1. PURPOSE

This SOP describes the procedure for preparing reports for Clinical Trials of an Investigational Medicinal Product (CTIMPs) and non-CTIMPs and complies with the principles of Good Clinical Practice (GCP).
The report covered is:

Annual Progress Report

From: Chief Investigator (CI)
To: Research Ethics Committee (REC) + copy to Sponsor

2. SCOPE

This SOP applies to TASC staff members, investigators and research staff working on CTIMPs and non-CTIMPs which are sponsored or co-sponsored by the University of Dundee and/or NHS Tayside.

3. RESPONSIBILITIES

This SOP complies with the requirements of the Medicines for Human Use (Clinical Trial) Regulations 2004 and subsequent amendments.

Progress reporting may be delegated to a third party, but this must be agreed between both parties and the responsibilities clearly documented before the study commences.

4. PROCEDURE

4.1 REC Annual Progress Reports (CTIMP)

4.1.1 Annual Progress Reports need to be submitted on the *Annual Progress Report Form for Clinical Trials of Investigational Medicinal Products* which is available on the Health Research Authority (HRA) website.

4.1.2 The completion and submission of the Annual Progress Report is the responsibility of the CI and should be submitted to the REC which gave a favourable opinion of the study.

4.1.3 Annual Progress Reports should be submitted annually, with the first report submitted 12 months after the date of the favourable opinion. The favourable opinion letter may/may not state conditions. Reports should be submitted thereafter until the end of the study. The report should be submitted on or within the next 30 days of the anniversary of the **first** letter from REC offering a favourable opinion.

4.1.4 If the study has not started within 12 months of the favourable opinion date (which may/may not be with conditions), an Annual Progress Report should be submitted with an explanation for the delay.

4.1.5 Progress Reports are only required for studies that are more than two years in duration. There is no requirement for a Progress Report where the study is two years or less in duration.

4.1.6 The receipt of the Annual Progress Report should be acknowledged by the REC coordinator.

4.1.7 A copy of the Annual Progress Report plus all correspondence should be filed in the Sponsor File and Trial Master File.

4.1.8 Following receipt of the first 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 REC Annual Progress Reports (non-CTIMP)

4.2.1 Annual Progress Reports for non-CTIMPs are the responsibility of the CI and should be submitted using the *Annual Progress Report Form for all Other Research* which is available from the Health Research Authority (HRA) website.

4.2.2 Annual Progress Reports should be submitted annually, with the first report submitted 12 months after the date of the favourable opinion. The favourable opinion letter may/may not state conditions. Reports should be submitted thereafter until the end of the study. The report should be submitted on or within the next 30 days of the anniversary of the first letter from REC offering a favourable opinion.

4.2.3 If the study has not started within 12 months of the favourable opinion date, (which may/may not be with conditions), an Annual Progress Report should be submitted with an explanation for the delay.

4.2.4 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 or where the study is two years or less in duration.

4.2.5 The receipt of the Annual Progress Report should be acknowledged by the REC coordinator.

4.2.6 A copy of the Annual Progress Report must be sent to Sponsor and lead NHS R&D.

4.2.7 Following receipt of the first 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.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HRA	Health Research Authority
R&D	Research & Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TASC	Tayside Medical Sciences Centre

6. ASSOCIATED DOCUMENTS & REFERENCES

None.

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
11	Patricia Burns (Senior Research Governance Manager)	28/09/2021	Change of title. DSUR section and reference to DSUR removed. This SOP is only for Annual Progress Reporting.
12	Patricia Burns(Senior Research Governance Manager)	28/09/2023	Change of title. Addition of text, section 4.1. 5 and 4.2.4, in line with HRA guidance on Progress Reports.

8. APPROVALS

Approved by:	Date:
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	27 Sep 2023