STANDARD OPERATING PROCEDURE FOR PREPARING AND WRITING A LABORATORY ANALYTICAL PLAN

SOP NUMBER:	TASC SOP036 v9
AUTHOR:	Valerie Godfrey
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1. PURPOSE

This Standard Operating Procedure (SOP) describes the preparation of an Analytical Plan (AP) for implementing analysis of laboratory samples from Clinical Trials of an Investigational Medicinal Products (CTIMP) as instructed in the study protocol. It is considered good practice for all University of Dundee (UoD) clinical research laboratories to follow this SOP

2. SCOPE

This SOP applies to clinical research staff who present samples from studies, sponsored or co-sponsored by UoD and NHS Tayside (NHST), to UoD and NHST laboratories for research analysis. The AP will not include laboratory activities for diagnostic purposes or for the routine clinical care of patients.

3. RESPONSIBILITIES

Chief Investigator (CI)/Principal Investigator (PI) is responsible for:

- discussing and producing an AP that describes the requirements of the study with regard to sample analysis from request to report (as described in the study protocol), prior to the start of the study.
- signing the AP.

Analytical Plan Manager (APM) is responsible for:

- ensuring the AP is based on the analysis described in the study protocol.
- ensuring that all laboratory staff, facilities, documents, resources, equipment and reagents will be available and fit for purpose.
- signing the AP.

TASC Quality Assurance (QA) Manager is responsible for:

- ensuring the AP is complete.
- ensuring that assays are covered in the TASC Lab Audit Schedule as required.
- signing the AP.

4. PROCEDURE

4.1 Prior to the start of a study, the CI/PI and a member of the laboratory staff, designated as the APM, should communicate to produce an AP. The AP will describe the requirements of the study with regard to sample analysis from request to report as described in the study protocol.

4.2 It is the responsibility of the APM to forward the AP to the TASC QA Manager. Upon agreement of the AP, all parties should sign and retain a copy. Copies should be kept in the Trial Master File and Sponsor File.

4.3 The following details should be included in an AP:

- Ask the question "Is this a CTIMP? Yes/No"
- Study title/code
- Names of CI/PI, APM and TASC QA Manager
- Research Ethics Committee (REC) Number
- NHS R&D number
- Number of patients, number of visits
- Type of sample(s) to be analysed
- Analytical test(s) to be performed:
    - Analytical tests should be marked accordingly as Primary or Secondary outcome measures
- Exploratory Research tests Yes/No
    - If Yes add details
- List of associated SOPs or equivalent documents
- Confirmation that written informed consent was obtained from each participant
- Sample storage conditions during analyses
- Details on what has to happen to the samples ultimately (post AP analysis)
- Duration of study
- Method of reporting results
- How long the trial data is to be archived for.
- How long the laboratory data is to be kept for.
- Confirmation that the list of analytes to be analysed are those described in study protocol.

4.4 A wide variety of tests may be requested and all SOPs or equivalents that are required to be followed should be included in the AP.

4.5 Where work at another location is involved, the name and address of the delegated scientist at this location should be stated and the nature of the work to be done.

4.6 Any modifications to the AP will be documented with reasons for doing so and signed by the APM. Modifications to the AP will not formally be reviewed and signed by the CI/PI and TASC QA Manager unless an updated version of the AP is necessary.

4.7 The APM will ensure that laboratory staff follow the AP and employ quality control checks as described in the SOPs and guidelines.

4.8 Prior to analysis the TASC QA Manager will be informed if there is a change to the analytical assays noted on the AP, this includes if assays are not carried out or if new ones have been added.

4.9 This information will give notice to the TASC QA Manager as to whether a new assay procedure is required to be added to the TASC Good Clinical Practice (GCP) Laboratory Audit Schedule. The TASC QA Manager or delegate will audit UoD and NHST clinical research laboratory facilities and processes in accordance with the current TASC GCP Laboratory Audit Schedules.

5. ABBREVIATIONS & DEFINITIONS

AP	Analytical Plan
APM	Analytical Project Manager
CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
GCP	Good Clinical Practice
NHST	NHS Tayside
PI	Principal Investigator
QA	Quality Assurance
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
UoD	University of Dundee

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:
7	Valerie Godfrey (TASC QA Manager)	17/02/2022	Text refreshed throughout, record if assays are for Primary, Secondary outcomes and/or Exploratory work. TASC QA Manager must be informed of any assays added or removed from the AP before analysis.
8	Valerie Godfrey (TASC QA Manager)	17/02/2024	Minor updates to text and removal of EudraCT number from the list in section 4.3.

9	Valerie Godfrey (TASC QA Manager)	17/02/2026	Vocabulary changed in line with ICH-GCP R3 updated terms.

8. APPROVALS

Approved by:	**Date:**
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	10 Feb 2026