STANDARD OPERATING PROCEDURE FOR PREPARATION OF AN ANALYTICAL PLAN FOR LABORATORIES ASSOCIATED WITH CLINICAL RESEARCH

SOP NUMBER:	**Fife R&D SOP29**
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1. PURPOSE

This document describes the procedure used for preparation of an Analytical Plan (AP) for implementing analysis of laboratory samples from clinical research in NHS Fife and complies with the principles of Good Clinical Practice (GCP).

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 tab of the Research, Innovation and Knowledge 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 document applies to all studies conducted in NHS Fife (sponsored and hosted) which involve the analysis of clinical research samples.

This document applies to staff responsible for presenting clinical research samples to NHS Fife laboratories for analysis.

3. POLICY

A clear undertaking that the NHS Fife Laboratory has agreed to perform the analysis or evaluation of clinical research samples must be agreed prior to the initiation of any sample collection. This must be detailed in an Analytical Plan (AP) using the 'Research Team – Laboratory Analytical Plan' workflow on EDGE or Doc Ref 29-01 (where access to EDGE is not available).

The AP will not include laboratory activities involved in routine clinical care of patients such as for diagnostic purposes.

4. PROCEDURE

4.1 Prior to the start of a study, the Chief Investigator (CI) or Principal Investigator (PI) must produce a draft AP and send this to the appropriate Laboratory(s) Manager(s) for review. The AP must describe the requirements of the study with regard to sample analysis from the point of submission of the request to issue of the lab report.

4.2 The following details must be included in an AP:

- Study title
- NHS Fife R&D number
- Contact details for CI or PI
- Study Synopsis
- Study timelines
- Sampling schedule - number of participants, number of visits
- Type of sample(s) to be analysed
- Location of sample collection, processing and storage
- Details of processing to be performed
- How details of processing will be recorded
- How samples will be identified as Research samples
- Analytical test(s) to be performed
- Confirmation that written informed consent for tissue samples will be obtained from participant (and for their long-term storage after the study ends, if applicable)
- Sample storage conditions prior to and during analyses
- Method of reporting laboratory results and how values outside of normal ranges will be highlighted to clinical teams
- Duration of sample storage - are samples to be disposed of or has consent been given for storage for future research?
- Duration of study data archive

4.3 A variety of tests may be requested and reference to any non-routine or external laboratory SOPs, guidelines and/or other appropriate documents should be included within the AP.

4.4 The Laboratory Manager must check that the tests listed on the AP match those in the study protocol and ensure that there are not any additional tests listed on the AP.

4.5 In the case of studies where samples require to be passed to another site(s) for further analysis, the contact details for this site(s) must be stated and the nature of the work to be done defined.

4.6 Upon agreement of the AP, both parties must sign it off and a copy must be retained in the Study Master File.

4.7 Amendments or deviations to the AP must be documented, with reasons for doing so, by the CI or PI and the Laboratory Manager.

4.8 The Laboratory Manager must ensure that analytical staff adhere to the AP and employ quality control procedures as described in the relevant laboratory SOPs and guidelines.

4.9 APs will be archived along with study documents when the study is complete.

5. ASSOCIATED DOCUMENTS

Doc Ref 29-01 – Laboratory Analytical Plan Template

6. ABBREVIATIONS

AP Analytical Plan
CI Chief Investigator
PI Principal Investigator
R&D Research and Development
SOP Standard Operating Procedure

7. REFERENCES

World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects.
(https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/)

Medicines for Human Use (Clinical Trials) Regulations 2004.
(http://www.legislation.gov.uk/uksi/2004/1031/contents/made)
It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.

8. DOCUMENT HISTORY

Version Number	Edited by (job title)	Effective Date	Details of Revisions Made
1	David Chinn Senior Research Advisor	31 Oct 2014	New - *Adapted from TASC SOP 36, version 2.0*
2	Julie Aitken R&D Trials Facilitator	10 Jun 2019	Reformatted in line with current SOP template. Revised to reflect current practice, to provide a process for both NHS Fife sponsored and hosted studies and to introduce a template for preparing an Analytical Plan.
3	Julie Aitken R&D Quality & Performance Manager	18 Jul 2022	Reference to 'Research Team - Laboratory Analytical Plan' Workflow on EDGE added.

9. APPROVAL

APPROVED BY	Date
Professor Frances Quirk, Assistant Director Research, Innovation & Knowledge, NHS Fife Signature: 	18 July 2022