



Institute of Primate Research

STANDARD OPERATING PROCEDURE (SOP) DOCUMENT

Statistical Analysis Plans (SAPs)

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Approvals

	Name	Signature	Date
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Table of Contents

1. PURPOSE.....	4
2. SCOPE	4
3. PERSONS RESPONSIBLE:	4
4. FREQUENCY.....	5
5. MATERIALS.....	5
6. PROCEDURE.....	5
7. REFERENCES	6

1. PURPOSE

To establish a standardized process for the preparation, review, approval, and version control of Statistical Analysis Plans (SAPs) for all research projects supported by the Data Science & Analytics Section (DS&AS).

This SOP ensures that all analyses are conducted according to pre-specified methodologies, thereby promoting **transparency, reproducibility, integrity, and regulatory compliance**. It also ensures that SAPs:

- Are aligned with the study design and ethical requirements outlined under **SOP 3: Study Design and Statistical Consultation**.
- Comply with institutional data governance frameworks and the Kenya Data Protection Act (2019).
- Reflect international best practices, including the **FAIR data principles**, **Good Clinical Practice (ICH E6[R3])**, and **WHO/CIOMS ethical guidelines**.
- Support accountability and auditability through version control, documentation, and linkage to project outputs and publications.

2. SCOPE

This SOP applies to all research projects supported by the Data Science & Analytics Section (DS&AS) that involve statistical analysis, modelling, or reporting, across biomedical, ecological, primatological, and translational studies.

It covers the full lifecycle of Statistical Analysis Plans (SAPs), including:

- Drafting based on approved study protocols.
- Review and approval by qualified DS&AS statisticians.
- Version control and archiving in the institutional repository.
- Documentation of any amendments prior to data analysis.

3. PERSONS RESPONSIBLE

- **Principal Investigator (PI):** Drafts the SAP in collaboration with DS&AS, ensuring that it accurately reflects the study objectives, endpoints, and planned analyses.
- **DS&AS Biostatistician/Data Scientist:** Develops and reviews the SAP, providing methodological guidance, statistical justification, and ensuring alignment with the study protocol.
- **Senior Statistician (DS&AS):** Reviews the SAP for scientific rigor and approves it prior to the commencement of data analysis.
- **Head of DS&AS:** Ensures that all SAPs are properly archived, version-controlled, and compliant with institutional policies and regulatory requirements.

4. FREQUENCY

- **Initial SAP Preparation:** Mandatory for every study before any data analysis begins.
- **Updates/Amendments:** Permitted only when justified (e.g., protocol changes or additional analyses) and must be **version-controlled, documented, and re-approved** by the Senior Statistician and Head of DS&AS.
- **Post-Approval Review:** SAPs should be reviewed periodically if substantial deviations from the original plan occur during the study.

5. MATERIALS

- **Analysis Plan (SAP) Template:** Includes objectives, endpoints, statistical methods, handling of missing data, and planned outputs.
- **Data Dictionary Template:** Standardized format for variable names, types, coding, and definitions to ensure consistency across datasets.
- **Dummy Tables / Shell Tables:** Pre-formatted tables outlining the expected structure and content of outputs for key analyses.
- **Version Control System:** Tools such as Git or the institutional repository to maintain version history and track amendments.
- **SAP Approval Form:** Standardized form for documenting review and sign-off by the Senior Statistician and Head of DS&AS.

- **Related Documentation:** Approved study protocol, ethical approval documents, prior SAPs, and any study-specific analysis notes.

6. PROCEDURE

- **Drafting:** PI, with DS&AS, drafts SAP based on approved protocol.
- **Review:** A senior statistician for methodological soundness reviews SAP.
- **Approval:** Head of DS&AS signs off before analysis begins.
- **Archiving:** SAP stored in central repository with version history.
- **Amendments:** Any updates must be justified, documented, and re-approved.
- **Link to Publication:** No results may be published without a corresponding approved SAP.

7. REFERENCES

1. KIPRE Strategic Plan (2023–2027)
2. DS&AS Policy and Strategy Framework (SOP 1)
3. SOP 2 – Alignment of DS&AS Processes with Institutional and National Regulations
4. SOP 3 – Study Design and Statistical Consultation
5. Kenya Data Protection Act (2019)
6. Institutional Data Protection and Sharing Policy (2024)
7. Good Clinical Practice (GCP) – ICH E6(R3) Guidelines
8. FAIR Data Principles (Findable, Accessible, Interoperable, Reusable)
9. CONSORT 2010 Statement – Consolidated Standards of Reporting Trials
10. STROBE Guidelines – Strengthening the Reporting of Observational Studies in Epidemiology
11. REMARK Guidelines – Reporting Recommendations for Tumour Marker Prognostic Studies
12. WHO and CIOMS International Ethical Guidelines for Health-Related Research (2016)

8. APPENDICES

Appendix 1: Statistical Analysis Plan (SAP) Template

Appendix 2: SAP Review and Approval Form

Appendix 3: SAP Version Control Log Template

Appendix 4: SAP Amendment Justification Form

Appendix 5: SAP–Publication Linkage Record Sheet