

**Institute of Primate Research**

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**STANDARD OPERATING PROCEDURE (SOP) DOCUMENT**

# ****Statistical Analysis Plans (SAPs)****

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| **Approvals** |  |  |  |
|  | **Name** | **Signature** | **Date** |
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# 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.

# 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.

# 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.

# 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.

# 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.

# 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.

# 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)

# ****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