Institute of Primate Research

STANDARD OPERATING PROCEDURE (SOP) DOCUMENT

Statistical Analysis Plans (SAPs)

SOP No.	Issue Number	Issue Date	Revision Status	Revision Date
SOP/KIPRE/RPD/DSAS/3.1.76	Version 01	October 2025	-	-

Approvals

	Name	Signature	Date
Developed by:	_Patrick Waweru Mwaura_	_____	_6th October; 2025_
	_____	_____	_____
	_____	_____	_____
Reviewed by:	_____	_____	_____
Approved by:	_____	_____	_____

Table of Contents

1. **PURPOSE**

 To mandate the preparation, approval, and version control of Statistical Analysis Plans (SAPs) before data analysis begins, ensuring transparency, reproducibility, and compliance.

2. **SCOPE**

Covers all research projects supported by DS&AS that involve statistical analysis, modelling, or reporting.

3. **PERSONS RESPONSIBLE:**

- **Principal Investigator (PI):** Drafts SAP with DS&AS support.
- **DS&AS Biostatistician/Data Scientist:** Develops and reviews SAP.
- **Senior Statistician (DS&AS):** Approves SAP before analysis.
- **Head of DS&AS:** Ensures archiving and compliance.

4. **FREQUENCY**

- **Mandatory once before any analysis begins.**
- **Updates allowed only with justification,** version-controlled and documented.

5. **MATERIALS**

- SAP template (including objectives, endpoints, statistical methods, handling of missing data).
- Version-control system (Git, institutional repository).
- Approval form.

6. **PROCEDURE**

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

7. **REFERENCES**

 To be provided later