

**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** |
| **Developed by:** | \_Patrick Waweru Mwaura\_ | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **\_6th October; 2025\_** |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
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| **Reviewed by:** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Approved by:** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

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# PURPOSE

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

# SCOPE

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

# 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.

# FREQUENCY

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

# MATERIALS

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

# PROCEDURE

1. **Drafting:** PI, with DS&AS, drafts SAP based on approved protocol.
2. **Review:** SAP is reviewed by a senior statistician for methodological soundness.
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.

# REFERENCES