Institute of Primate Research

STANDARD OPERATING PROCEDURE (SOP) DOCUMENT

Study design and statistical consultation

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 ensure that all research studies supported by the Data Science and Analysis Support (DS&AS) Unit are designed with sound statistical principles and align with the overarching policies and strategies outlined in **SOP 1**.

This SOP operationalizes those principles by providing structured guidance on developing rigorous study designs that meet ethical and regulatory requirements (as detailed in **SOP 2**) while optimising efficiency, reproducibility, and scientific validity.

2. SCOPE

This SOP applies to all KIPRE researchers and collaborators seeking statistical consultation from the Data Science and Analysis Support (DS&AS) Unit. It covers study design and statistical guidance for biomedical, ecological, primatological, and translational research projects, from initial concept development to protocol finalization.

3. PERSONS RESPONSIBLE

- **Principal Investigator (PI):** Initiates statistical consultation by submitting the study concept, objectives, and draft protocol to DS&AS.
- **DS&AS Biostatistician/Statistician:** Provides methodological guidance on study design, sampling, data collection, and analysis strategies.
- **Head of DS&AS:** Reviews and approves the final study design recommendations and ensures alignment with institutional and regulatory requirements.
- **Ethics Committee/IRB:** Evaluates the scientific validity and ethical soundness of the proposed study design before approval.

4. FREQUENCY

- **Before study initiation:** Mandatory statistical consultation for all new projects prior to ethical approval and data collection.
- **Mid-study (as needed):** Additional consultations required when protocol amendments, sample size adjustments, or major analytical changes are proposed.
- **Post-study (optional):** Consultation may be sought during result interpretation or manuscript preparation to ensure statistical accuracy and reproducibility.

5. MATERIALS

- Standard research protocol template.
- Sample size and power calculation tools (e.g., R, SAS).
- Ethical approval and regulatory guidelines (IRB/NACOSTI).
- DS&AS Statistical Consultation Request Form.
- Relevant institutional and project-specific data management policies.

6. PROCEDURE

Step 1: Request Submission

• The Principal Investigator (PI) submits a study concept note or draft protocol to DS&AS using the Statistical Consultation Request Form.

Step 2: Preliminary Review

• DS&AS assigns a qualified Biostatistician/Statistician to review the study objectives, hypotheses, and proposed methodology.

• Any missing information or unclear sections are communicated to the PI for clarification.

Step 3: Consultation Meeting

• A consultation session is held between the PI and the assigned biostatistician to discuss study objectives, design options, sampling strategies, and appropriate statistical methods.

• Ethical and regulatory considerations (as per SOP 2) are reviewed during the meeting.

Step 4: Design Specification and Recommendations

• The Biostatistician prepares written recommendations outlining the final study design, sample size justification, analytical plan, and any simulation requirements.

Step 5: Review and Approval

• The Head of DS&AS reviews the design recommendations for scientific rigor and compliance with institutional and national standards before sign-off.

• The approved design forms part of the official study protocol submitted to the IRB/NACOSTI.

Step 6: Archiving and Documentation

• All consultation notes, communications, and final design recommendations are archived in the DS&AS project repository.

• Records are maintained in accordance with institutional data governance policies for traceability and future reference.

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. Kenya Data Protection Act (2019)
5. National Commission for Science, Technology and Innovation (NACOSTI) Research Guidelines
6. Institutional Review Board (IRB) Ethical Review Framework
7. FAIR Data Principles (Findable, Accessible, Interoperable, Reusable)
8. World Health Organization (WHO) and Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Health-Related Research (2016)
9. International Council for Harmonization (ICH) E6(R3) – Good Clinical Practice (GCP) Guidelines

Appendix 1: DS&AS Statistical Consultation Request Form

Appendix 2: Study Design Review and Approval Template

Appendix 3: Sample Size and Power Calculation Record Sheet

Appendix 4: Consultation Summary and Recommendation Report Template

Appendix 5: DS&AS Project Repository Archiving Checklist