

**Institute of Primate Research**

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**STANDARD OPERATING PROCEDURE (SOP) DOCUMENT**

**Study Design and Statistical Consultation**

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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 ensure that all research studies supported by DS&AS are designed with sound statistical principles, aligned with ethical and regulatory requirements, and optimized for efficiency, reproducibility, and validity.

# SCOPE

Applies to all researchers at KIPRE and collaborators seeking statistical consultation from DS&AS for biomedical, ecological, primatological, and translational studies.

# PERSONS RESPONSIBLE:

* **Principal Investigator (PI):** Initiates consultation and provides study objectives and protocols.
* **DS&AS Biostatistician/Statistician:** Provides study design, sampling strategy, and statistical methodology support.
* **Head of DS&AS:** Approves final design consultation recommendations.
* **Ethics Committee:** Reviews designs for compliance with ethical standards.

# FREQUENCY

* **Before study initiation** – Mandatory consultation for every project.
* **Mid-study (as needed)** – When changes to protocol/sample size/analysis plan arise.

# MATERIALS

* Research protocol template.
* Sample size and power calculation tools (R, SAS).
* Ethical approval guidelines (IRB/NACOSTI).
* DS&AS statistical consultation request form.

# PROCEDURE

1. **Request Submission:** PI submits study concept note or protocol draft to DS&AS.
2. **Preliminary Review:** DS&AS assigns a biostatistician for initial review.
3. **Consultation Meeting:** DS&AS and PI discuss objectives, design options, and statistical methods.
4. **Design Specification:** Biostatistician provides written recommendations (design type, sample size, analysis methods).
5. **Approval & Documentation:** Head of DS&AS reviews and signs off before protocol submission to IRB.
6. **Archiving:** All consultation notes are stored in the DS&AS project repository

# REFERENCES