



Institute of Primate Research

STANDARD OPERATING PROCEDURE (SOP) DOCUMENT

Study design and statistical consultation

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Approvals

	Name	Signature	Date
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1. 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.

2. SCOPE

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

3. 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.

4. FREQUENCY

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

5. MATERIALS

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

6. 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

7. REFERENCES

To be provided later