Institute of Primate Research

STANDARD OPERATING PROCEDURE (SOP) DOCUMENT

Alignment of DS&AS processes with Institutional and National Regulations

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
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1. PURPOSE

To provide a standardized procedure for ensuring that all DS&AS processes, including data collection, storage, analysis, sharing, and reporting, comply with the Kenya Data Protection Act (2019), institutional data governance policies, ethical standards, and international best practices.

2. SCOPE

This SOP applies to all DS&AS operations across biomedical, ecological, and conservation research projects. It covers:

- Compliance with **Kenya Data Protection Act (2019)** and institutional data-sharing policies.
- Ethical approvals from recognized **Institutional Review Boards (IRBs)** and the **National Commission for Science, Technology and Innovation (NACOSTI)**.
- Alignment with international data governance standards (e.g., FAIR, GDPR, WHO ethics guidelines).
- Documentation of compliance checks across all DS&AS-supported projects.

3. PERSONS RESPONSIBLE:

- **Head of DS&AS** – Ensures overall compliance and reports to the Director of Research and Product Development.
- **Data Protection Officer (DPO)** – Provides oversight on adherence to the Data Protection Act and institutional policies.
- **DS&AS Compliance Officer / Assigned Analyst** – Conducts routine compliance checks.
- **Principal Investigators (PIs)** – Ensure that project-level processes (study design, data collection, analysis) meet ethical and legal requirements.
- **Ethics Review Committees & Regulators** – Provide external approvals and oversight.

4. FREQUENCY

- **Before project initiation** – Compliance checks on ethical approvals, consent forms, and data collection methods.
- **During project implementation** – Continuous monitoring of data handling, access, and sharing.
- **Annual compliance review** – DS&AS and DPO audit all ongoing projects.
- **Triggered updates** – Immediately after any legal/regulatory amendments (e.g., revisions to the DPA 2019).

5. MATERIALS

- Kenya Data Protection Act (2019) and regulations.

- KIPRE's Institutional Data Protection and Sharing Policy.
- NACOSTI guidelines and ethics approval frameworks.
- Institutional Review Board (IRB) protocols.
- Compliance checklist templates.
- Data governance dashboards and monitoring tools.

6. PROCEDURE

Step 1: Pre-Project Compliance Review

- PI submits study protocol and data management plan.
- DS&AS verifies alignment with institutional policies, DPA 2019, and ethical requirements.
- Required approvals (IRB, NACOSTI) must be documented before project initiation.

Step 2: Ongoing Compliance Monitoring

- DS&AS tracks data handling workflows via compliance dashboards.
- Access to sensitive datasets restricted through role-based controls and encryption.
- Regular audits ensure adherence to consent requirements, anonymisation standards, and secure transfer protocols.

Step 3: Breach and Incident Handling

- In case of data breach, DS&AS coordinates with ICT and DPO for immediate containment.
- Notify authorities and affected parties within **72 hours** (as per DPA 2019).
- Document incident, corrective measures, and lessons learned.

Step 4: Annual and Ad-Hoc Reviews

- DS&AS and DPO jointly conduct an annual compliance audit across all projects.
- Review includes data quality, security controls, ethical approvals validity, and adherence to FAIR principles.
- Interim reviews are triggered by regulatory changes or identified risks.

Step 5: Reporting & Documentation

- Compliance reports prepared by DS&AS and submitted to the Director of Research and Product Development.
- Copies archived in the institutional compliance repository.
- Findings disseminated to staff during compliance workshops.

Step 6: Continuous Capacity Building

- DS&AS organizes training on compliance requirements for all researchers.
- Refresher sessions conducted annually and whenever regulatory updates occur.

7. REFERENCES

To be provided later.