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
Developed by:	_Patrick Waweru Mwaura_	_____	_6th October; 2025_
	_____	_____	_____
	_____	_____	_____
Reviewed by:	_____	_____	_____
Approved by:	_____	_____	_____

Table of Contents

1. **PURPOSE**

   To ensure that all operational processes within the DS&AS are implemented in full compliance with the policies and strategic directions outlined in **SOP 1: Data Analytics Policies and Strategies**.

   This SOP translates those policies into practice by guiding the alignment of DS&AS activities—including data collection, storage, processing, analysis, sharing, and reporting—with institutional requirements, the **Kenya Data Protection Act (2019)**, and relevant international standards such as the **FAIR Data Principles**, **GDPR**, and **21 CFR Part 11**.

   It provides a structured mechanism for maintaining legal, ethical, and institutional conformity across all DS&AS-supported projects, thereby promoting responsible data stewardship, accountability, and sustainable research practices.

2. **SCOPE**

   This SOP applies to all operational processes and projects within the Data Science & Analytics Section (DS&AS), including biomedical, ecological, and conservation research activities. It provides the implementation framework for **SOP 1**, ensuring that all DS&AS operations conform to applicable legal, ethical, and institutional requirements.

   Specifically, it covers:

   - Compliance with the **Kenya Data Protection Act (2019)**, institutional data governance, and data-sharing policies.
   - Obtaining and maintaining **ethical approvals** from recognized Institutional Review Boards (IRBs) and the **National Commission for Science, Technology and Innovation (NACOSTI)**.
   - Alignment with **international data governance and ethical standards**, including the FAIR Data Principles, GDPR, and WHO research ethics frameworks.
   - Systematic **documentation and verification of compliance checks** across all DS&AS-supported research and data analytics activities.

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:** Conduct compliance checks to verify ethical approvals, informed consent forms, and data collection procedures.
- **During Project Implementation:** Maintain continuous oversight of data handling, access control, sharing practices, and adherence to approved protocols.
- **Annual Compliance Review:** The DS&AS, in collaboration with the Data Protection Officer (DPO), performs annual audits of all active projects to assess ongoing conformity.
- **Triggered Updates:** Implement immediate reviews and procedural updates following amendments to the **Kenya Data Protection Act (2019)** or related institutional or international regulatory changes.

5. MATERIALS

- **Kenya Data Protection Act (2019)** and associated implementing regulations.
- **KIPRE Institutional Data Protection and Sharing Policy.**
- **NACOSTI** research and ethics approval frameworks.
- **Institutional Review Board (IRB)** protocols and guidance documents.
- Standard **compliance checklists** for DS&AS projects.
- **Data governance dashboards** and digital monitoring tools used for compliance tracking.

6. PROCEDURE

- **Step 1: Pre-Project Compliance Review**
  • The Principal Investigator (PI) submits the study protocol and data management plan to DS&AS.
  • DS&AS reviews the submission for conformity with institutional policies, the Kenya Data Protection Act (2019), and relevant ethical standards.
  • All mandatory approvals from the Institutional Review Board (IRB) and NACOSTI must be secured and documented before project initiation.

- **Step 2: Ongoing Compliance Monitoring**
  • DS&AS continuously tracks data handling processes through compliance dashboards and audit tools.
  • Access to sensitive data is managed using role-based controls, encryption, and secure authentication mechanisms.
  • Periodic audits verify adherence to consent provisions, anonymisation protocols, and approved data transfer procedures.

- **Step 3: Breach and Incident Handling**
  • In the event of a data breach or security incident, DS&AS coordinates with the ICT Department and the Data Protection Officer (DPO) to ensure immediate containment and mitigation.
  • Notifications to regulatory authorities and affected data subjects must be issued within 72 hours, as stipulated in the Kenya Data Protection Act (2019).
  • Each incident must be fully documented, including corrective actions and lessons learned.

- **Step 4: Annual and Ad-Hoc Reviews**
  • DS&AS and the DPO conduct an annual compliance audit covering all active research and data analytics projects.
  • The review assesses data quality, information security controls, validity of ethical approvals, and adherence to the FAIR Data Principles.
  • Ad-hoc reviews may be initiated in response to legal or policy changes, detected risks, or internal audit findings.

- **Step 5: Reporting and Documentation**
  • Compliance reports are prepared by DS&AS and submitted to the Director of Research and Product Development for institutional review.
  • All reports and supporting evidence are archived in the institutional compliance repository.
  • A summary of key findings is shared with staff through compliance awareness workshops.

- **Step 6: Continuous Capacity Building**
  • DS&AS conducts regular training sessions for staff and researchers on evolving

compliance and data governance requirements.
• Refresher courses are organized annually and whenever significant regulatory or institutional updates occur.

6. REFERENCES

1) Kenya Data Protection Act (2019). Government of Kenya, Nairobi.

2) Kenya Data Protection (General) Regulations (2021). Office of the Data Protection Commissioner (ODPC).

3) Science, Technology and Innovation Act (2013). National Commission for Science, Technology and Innovation (NACOSTI).

4) KIPRE Institutional Data Protection and Sharing Policy (2024). Kenya Institute of Primate Research (KIPRE).

5) Institutional Review Board (IRB) Guidelines and Standard Operating Procedures. KIPRE.

6) SOP 1: Data Analytics Policies and Strategies. Data Science & Analytics Section (DS&AS), KIPRE.

7) FAIR Data Principles. GO FAIR Initiative, 2016.

8) General Data Protection Regulation (GDPR) (EU) 2016/679. European Parliament and Council of the European Union.

9) Title 21, Code of Federal Regulations, Part 11 (21 CFR Part 11). U.S. Food and Drug Administration (FDA).

10) Health Insurance Portability and Accountability Act (HIPAA) of 1996. U.S. Department of Health and Human Services.

11) World Health Organization (WHO) Guidelines on Ethics in Health Research. WHO, Geneva.

12) Federal Information Security Management Act (FISMA) of 2002 (amended 2014). U.S. Congress.

7. APPENDIX: COMPLIANCE AND DOCUMENTATION FORMS

The following standard forms and templates shall support the implementation of this SOP:

1. **Pre-Project Compliance Review Form**

To document ethical approvals, consent templates, and alignment with institutional and legal requirements prior to project initiation.

2. **Data Handling and Access Control Log**

To record user access permissions, encryption status, and any data-sharing events during project implementation.

3. **Compliance Monitoring Checklist**

Used by DS&AS and the Data Protection Officer (DPO) to assess ongoing compliance with data protection and ethical standards.

4. **Data Breach and Incident Report Form**

To document details of any data breach or incident, corrective actions taken, and communication with regulatory bodies (e.g., ODPC).

5. **Annual Compliance Audit Report Template**

To standardize reporting of annual audit findings, including risk assessment outcomes and recommendations.

6. **Ad-Hoc Review Trigger Form**

Used to initiate unscheduled reviews following regulatory updates, emerging risks, or internal audit findings.

7. **Compliance Training Attendance Record**

To record participation of DS&AS staff and researchers in compliance and data governance training sessions.

8. **Compliance Reporting and Submission Form**

For submission of final compliance reports to the Director of Research and Product Development and archiving in the institutional repository.