



Institute of Primate Research

STANDARD OPERATING PROCEDURE (SOP) DOCUMENT

**Development, review, and updating of DS&AS policies
and strategies**

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Approvals

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1. PURPOSE

To establish a standardized and transparent process for the development, review, and continuous improvement of data analytics policies and strategies within the Data Science & Analytics Section (DS&AS), ensuring alignment with:

- **The Kenya Data Protection Act (2019)** – providing the national legal framework for the protection of personal data and the regulation of data processing activities within Kenya.
- **Institutional data governance frameworks and regulations** – ensuring compliance with internal policies, ethical standards, and accountability requirements.
- **The FAIR Data Principles** – promoting data that are *Findable*, *Accessible*, *Interoperable*, and *Reusable* to enhance data stewardship, transparency, and reproducibility in research.
- **Title 21, Code of Federal Regulations, Part 11 (21 CFR Part 11)** – establishing the U.S. Food and Drug Administration (FDA) requirements for the trustworthiness, reliability, and equivalence of electronic records and electronic signatures.
- **The General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679)** – governing the protection of personal data and privacy for individuals within the European Union and the European Economic Area, including the regulation of international data transfers.
- **The Health Insurance Portability and Accountability Act (HIPAA) of 1996** – setting the U.S. standards for safeguarding the privacy and security of protected health information (PHI) in healthcare and biomedical research.
- **The Federal Information Security Management Act (FISMA) of 2002** (amended 2014) – requiring U.S. federal agencies and their partners to implement comprehensive information security programs to protect government information systems and data assets.

2. SCOPE

This SOP applies to all staff within the Data Science & Analytics Section (DS&AS) involved in the formulation, review, implementation, and periodic evaluation of data analytics policies and strategies.

It covers policies and procedures related to:

- **Data governance and management**, including data lifecycle management, access control, and stewardship.
- **Data analytics, modelling, and reproducibility standards**, ensuring methodological transparency and consistency.
- **Ethical data use and compliance** with national and international regulatory frameworks, including the Kenya Data Protection Act (2019), HIPAA, FISMA, GDPR, and 21 CFR Part 11.
- **Data quality, integrity, and security assurance**, in line with institutional and global best practices.
- **Alignment with KIPRE's strategic goals**, national health and research priorities, and internationally recognized standards such as the FAIR Data Principles.

3. PERSONS RESPONSIBLE:

- **Head of DS&AS** – Leads policy development and review process; ensures compliance.
- **Policy Development Committee (PDC)** – Comprised of DS&AS representatives, Data Protection Officer (DPO), ICT lead, and legal/ethics officer.
- **Director of Research and Product Development** – Provides approval before institutional adoption.
- **External Stakeholders (as needed)** – Regulators, ethics review committees, collaborating partners for consultation.

4. FREQUENCY

- **Policy Development:** Conducted as needed to address emerging requirements, new technologies, or changes in operational, legal, or regulatory frameworks.

- **Policy Review:** Undertaken annually by the Data Science & Analytics Section (DS&AS), with a comprehensive institutional review every three (3) years, consistent with KIPRE’s policy review cycle.
- **Interim Updates:** Initiated when significant amendments occur in applicable laws or regulations (e.g., Kenya Data Protection Act, HIPAA, GDPR, or 21 CFR Part 11) or when new international standards or best practices emerge that affect DS&AS operations.

5. MATERIALS

The following documents and resources shall be used to guide the development, review, and updating of DS&AS data analytics policies and strategies:

- **KIPRE Strategic Plan (2023–2027)** – outlining institutional priorities, strategic objectives, and alignment with national research goals.
- **DS&AS Strategic Framework and Policy Proposal** – defining the Section’s operational focus, data strategy, and implementation roadmap.
- **Kenya Data Protection Act (2019)** and other relevant **ICT and Research Acts** – providing the legal framework for data protection, processing, and governance within Kenya.
- **Institutional Data Protection and Data Sharing Policy (2024)** – establishing institutional procedures and standards for ethical data management and sharing.
- **International Standards and Guidelines**, including:
 - FAIR Data Principles (Findable, Accessible, Interoperable, Reusable)
 - General Data Protection Regulation (GDPR; Regulation (EU) 2016/679)
 - Royal Statistical Society (RSS) Professional and Ethical Guidelines
 - World Health Organization (WHO) and American Statistical Association (ASA) Research Ethics Frameworks
 - Title 21, Code of Federal Regulations, Part 11 (21 CFR Part 11)
 - Health Insurance Portability and Accountability Act (HIPAA)
 - Federal Information Security Management Act (FISMA)
- **Standard Templates and Tools:**
 - Policy Draft Template
 - Policy Review Checklist
 - Policy Approval and Endorsement Form

6. PROCEDURE

Step 1: Needs Assessment

- Identify policy and strategy gaps through continuous monitoring, audits, user feedback, and performance evaluations.
- Benchmark existing practices against national legislation, institutional frameworks, and international standards (e.g., FAIR principles, GDPR, HIPAA, FISMA, and 21 CFR Part 11).
- Prioritize identified needs based on operational significance, compliance risk, and emerging data trends.

Step 2: Drafting

- The DS&AS prepares a draft policy or strategy document using the approved institutional policy template.
- Integrate provisions for data access and sharing, security and anonymisation, quality assurance, governance workflows, and compliance with applicable laws and ethical guidelines.
- Ensure alignment with KIPRE's strategic goals and data stewardship objectives.

Step 3: Internal Review

- The Policy Development Committee (or designated subcommittee) reviews the draft for technical accuracy, legal soundness, and ethical compliance.
- Feedback is consolidated, and necessary revisions are made to strengthen the document before external circulation.

Step 4: External Consultation

- Where applicable, circulate the revised draft to relevant ethics committees, data protection officers, regulatory bodies, and external partners for expert input.
- Document all feedback, decisions, and modifications in a review log to maintain transparency and traceability.

Step 5: Approval

- Submit the final draft to the Director of Research and Product Development and institutional leadership for official review and approval.
- Ensure that all approval records are documented and archived in accordance with institutional data governance procedures.

Step 6: Dissemination

- Publish the approved policy on KIPRE's intranet, data governance portal, or other designated platforms.
- Conduct staff sensitization sessions and targeted training workshops to ensure awareness and compliance with new or revised policies.

Step 7: Monitoring and Review

- The DS&AS monitors policy implementation through routine audits, performance indicators (KPIs), and data governance dashboards.
- Review and update policies as necessary following the annual or comprehensive 3-year review cycle, or when triggered by regulatory or operational changes.

7. REFERENCES

The following key documents and regulatory frameworks shall guide the development, implementation, and review of DS&AS data analytics policies and strategies:

1. Kenya Data Protection Act (2019) – Government of Kenya.
2. KIPRE Strategic Plan (2023–2027) – Kenya Institute of Primate Research.
3. Institutional Data Protection and Data Sharing Policy (2024) – KIPRE.
4. Data Science & Analytics Section (DS&AS) Strategic Framework and Policy Proposal – KIPRE.
5. FAIR Guiding Principles for Scientific Data Management and Stewardship – Wilkinson et al., *Scientific Data*, 2016.
6. Title 21, Code of Federal Regulations, Part 11 (21 CFR Part 11) – U.S. Food and Drug Administration (FDA).

7. General Data Protection Regulation (GDPR) – Regulation (EU) 2016/679 of the European Parliament and Council.
8. Health Insurance Portability and Accountability Act (HIPAA) – U.S. Department of Health and Human Services (HHS), 1996.
9. Federal Information Security Management Act (FISMA) – U.S. Congress, 2002 (amended 2014).
10. Royal Statistical Society (RSS) Code of Conduct and Professional Ethics – RSS, United Kingdom.
11. World Health Organization (WHO) and American Statistical Association (ASA) Research Ethics Guidelines.
12. Institutional Standard Operating Procedure Manual – KIPRE.

Note: This section shall be updated periodically to reflect new or revised laws, standards, and institutional policies relevant to DS&AS operations.