SOP: Data Recording and Result Documentation Process

This SOP details the **data recording and result documentation process**, encompassing systematic collection, accurate entry, validation, and secure storage of data, as well as comprehensive documentation of results. It aims to ensure data integrity, traceability, and compliance with regulatory standards, facilitating reliable analysis and informed decision-making throughout the project lifecycle.

1. Purpose

To define the standardized procedures for collecting, recording, validating, and storing data, and for documenting results to ensure accuracy, reliability, and compliance with applicable regulations.

2. Scope

This SOP applies to all project personnel involved in data generation, entry, verification, storage, and reporting activities throughout the project lifecycle.

3. Responsibilities

- **Project Manager:** Ensure compliance and training.
- **Data Entry Personnel:** Accurately collect and enter data.
- **Quality Assurance (QA):** Validate accuracy and completeness of recorded data and documentation of results.
- **IT/Data Manager:** Secure storage, backup, and access control of data and documentation.

4. Procedure

1. **Data Collection**
   - Define data collection parameters and sources in the project plan.
   - Use approved forms, logs, or digital systems for real-time data capture.
   - Assign unique identifiers to ensure data traceability.
2. **Data Recording & Entry**
   - Record data promptly, legibly, and accurately.
   - Enter data into designated electronic systems or secure physical records.
   - Date and sign/initial all entries; for digital entries, use audit-trail-enabled accounts.
3. **Data Validation & Correction**
   - Verify entries for completeness, consistency, and accuracy.
   - Document and correct errors using approved correction procedures (e.g., single strike-through, reason for correction, initials, date).
4. **Result Documentation**
   - Summarize results clearly in accordance with reporting formats.
   - Attach or reference supporting documentation and raw data files.
   - Include interpretation, conclusions, and, where applicable, recommendations.
5. **Data Storage & Security**
   - Store original data, results, and supporting documents in secure, access-controlled environments.
   - Implement regular backups for electronic data; ensure physical records are protected from loss, damage, or unauthorized access.
   - Retain data per defined retention policy and regulatory requirements.
6. **Audit Trail & Traceability**
   - Maintain comprehensive and traceable records of all data capture, edits, and analyses.
   - Ensure all modifications are logged (for digital systems, via audit trails).

5. Documentation and Forms

Document/Form	Description	Retention Period
Data Collection Log	Original record of collected data (paper/electronic)	Project duration + minimum 5 years
Correction Log	Record of all data corrections and justifications	Project duration + minimum 5 years

Results Report Template	Standardized template for result documentation	Project duration + minimum 5 years
Access Log	Record of access to data storage	Project duration + minimum 5 years

6. References

- Company Data Management Policy
- Applicable Regulatory Guidelines (e.g., GxP, ISO standards)

7. Revision History

Version	Date	Description of Change	Approved By
1.0	2024-06-27	Initial SOP release	[Name/Signature]