



National Institute of
Diabetes and Digestive
and Kidney Diseases

Standard Operating Procedures for High-Quality Data Collection

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August 27th, 2026



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Learning Objectives

- Describe the role of SOPs in standardized data collection
- Identify the key components of effective data collection SOPs
- Apply standardized procedures for documenting missing, invalid, and unusable data.
- Recognize how standardized collection procedures support high-quality, reproducible research data.

Standard Operating Procedures (SOP) for Data Collection

- What is an SOP?
 - An SOP is a written document that provides standardized step-by-step instructions for collecting, documenting, and managing study data.
- Why use SOPs?
 - Standardize procedures across personnel and study sites
 - Improve consistency and reproducibility
 - Reduce variability and errors
 - Support staff training and operational continuity
 - Promote data quality and regulatory compliance

Common Challenges Addressed by SOPs



Measurement

- Units
- Precision
- Equipment
- Timing



Laboratory

- Detection limits (LOD)
- Assay ranges
- Specimen collection



Data Collection

- Missing data
- Data entry
- Deviations
- Documentation



Personnel

- Training
- Version control
- Standardized procedures

Why SOPs are Important

Without SOP

- ✗ Inconsistent collection procedures
- ✗ Inconsistent documentation
- ✗ Variable data quality
- ✗ Increased measurement error
- ✗ Inconsistent staff training
- ✗ More data corrections
- ✗ Greater regulatory and audit risk

With SOP

- ✓ Standardized collection procedures
- ✓ Standardized documentation
- ✓ High-quality, reliable data
- ✓ Improved measurement accuracy
- ✓ Consistent staff training
- ✓ Fewer data corrections
- ✓ Regulatory and audit readiness

SOPs in Practice

Without clear SOPs, small differences in data collection and documentation can lead to inconsistent study data.

Metric Discrepancies

Height recorded in inches vs. centimeters

Timing Variations

Blood pressure measured after a 5-minute rest vs. immediately after walking

Interpretation Inconsistencies

<LOD recorded as 0 vs. left blank

Documentation Ambiguity

Equipment failure: "Not measured" vs. "Invalid measurement"

🛡️ **Standardized Results (With SOP)**

- ✓ **Standardized collection procedures** ensure consistent data collection
- ✓ **Standardized documentation** improves data completeness
- ✓ **Consistent interpretation** supports reliable data
- ✓ **Higher-quality data** strengthens study validity

Components of an Effective SOP

Planning

- Purpose and scope
- Roles and responsibilities

Data Collection

- Equipment and materials
- Collection procedures

Documentation

- Required fields
- Units and acceptable ranges

Quality Control

- Missing data and protocol deviations
- Corrective actions

Common Sections of an SOP

- Purpose and scope
- Background information and definitions
- Personnel roles and responsibilities
- Materials, tools, and equipment
- Related guidelines, policies, and reference documents
- Procedures
- Version control

Examples of Common SOPs

- Participant screening and enrollment
- Study assessments
- Biospecimen collection and processing
- Laboratory procedures
- Sample storage and shipping
- Equipment operation and calibration
- Data collection and management
- Missing data handling

Standardizing Missing Data Documentation

- Missing data can occur for many reasons:
 - Participant no-show, withdrawal, or lost to follow-up
 - Procedure not performed or incomplete visit
 - Measurement or equipment error
 - Not applicable (protocol or skip pattern)
 - Participant refused
 - Unresolved
- Each situation has a different meaning and should be documented consistently.
- Consistent definitions improve data quality and interpretation.

Example Missing Data SOP

- Defines standardized missing-data categories
- Specifies when missingness should be documented
- Requires documentation of the reason for missing data
- Promotes consistent documentation across study staff

1. Missingness status field (e.g., pbi missing)

- This is a dropdown field with predefined options that describe the overall missingness status of the form (options described below).
- The default value is “**Not Missing**” and should be updated whenever any part of the form has missing or unusable data.

2. Missingness comments field (e.g., pbi comments)

- This is a free-text field in which study staff should document a brief explanation of the circumstances leading to the missing or unusable data on the form.
- Comments should be specific enough to justify the selected missingness status and to support later data cleaning and analysis.

SOP excerpt

Implementing the Missing Data SOP in REDCap

- REDCap operationalizes the SOP by requiring study staff to:
 - Select the appropriate missing-data category
 - Document the reason for missing data

The screenshot shows the REDCap interface for configuring a field named 'chmbr_missing'. The field is labeled 'Chamber Missing' and has a red asterisk indicating it is required. Below the field name, there is a dropdown menu with a list of missing data categories. The categories are: 'Not missing' (highlighted in blue), 'Respondent not found/No-Show/Lost to follow-up/Withdrawn', 'Not measured/Incomplete Visit', 'Value out of range', 'Measurement error', 'Not Applicable/Skip pattern', 'Don't know/refused', and 'Missing unresolved'. The interface also shows a field named 'chmbr_comments' below it.

REDCap integrates SOP requirements into the data collection workflow.

Example Study Procedure SOP

- Standardizes the order of study procedures
- Standardizes repeated measurements and measurement precision

Repeated Circumference Measurement Order

1. Circumference measurements must be performed in the following order and repeated as complete rounds:
 - **Round 1:** Neck → Waist → Hip
 - **Round 2:** Neck → Waist → Hip
 - **Round 3:** Neck → Waist → Hip

Do **not** take three consecutive measures at the same site. For example, do not measure neck three times in a row. Complete the full sequence before repeating the next round.

Record each measurement to the nearest 0.1 cm in the appropriate data collection instrument/Redcap.

Best Practices & Takeaways

- Questions to consider when developing an SOP
 - Could two coordinators perform this procedure differently?
 - Are units and acceptable ranges defined?
 - Is missing data handled consistently?
 - Would another researcher understand these data five years from now?
- Effective SOPs promote:
 - Consistency
 - Accuracy
 - Reproducibility
 - Traceability
- Well-designed SOPs standardize data collection and documentation to support high-quality, reliable data throughout the research process.