

Job Aid #4: General Rules for SOP Writing

Control the language so that every word counts and messages are clear to readers.

Processes should flow in logical (and usually chronological) order.

Write to two different audiences.

- SOP User:
 - Write the information that is needed to get the job done. Try to avoid long, complex sentences.
 - Make use of bullets for ideas you want to stand out.
- Auditor or Regulatory Inspector/Investigator:
 - Ensure all critical steps are covered.
 - Ensure ideas are presented clearly and unambiguously. Don't give the auditor something to cite, simply because you wrote your sentence poorly.

Specify "SOP roles" – not job titles or staff member names.

For example, "project statistician" indicates the statistician assigned to the project is responsible for an SOP task – it doesn't matter whether they're a senior or principal level statistician.

- Use "or designee" for tasks that can be delegated under the oversight of a specific role.
- Create a matrix between SOP roles and designees to their respective job titles to ensure training requirements are identified.

Write in the third person, active voice, present tense; and make the text in the documents clear and logical.

- Write SOPs from the *third-person* point of view.
 - Avoid: You, I, and we
 - Use: Roles, titles (sometimes)
- Write *active* rather than *passive* sentences and assign responsibility for actions.
 - Do use: The PM obtains the needed signatures and ensures the form is maintained in the project trial master file.
 - Do not use: The form is completed and filed.

Use the imperative voice to avoid the need for "should" and "must."

Some Examples:

- When the **protocol development lead** is satisfied that all the issues that can be addressed by the study team have been addressed, **he or she submits** the draft protocol to the protocol review committee.
- The **CRA promptly reports** to the lead CRA or PM, protocol or regulatory deviations that require immediate attention, review, and determination of subject status.

Duplication should be avoided when it causes confusion but should be used when needed for consistency.

- Cover each segment of the task only once.
- When steps are repeated, either refer to the previous steps or use the same language. ***If you are saying the same thing, say it the same way.***
*e.g., "When the plan is updated, the lab manager ensures it is reviewed and approved **as specified in section 3.8.**"*

Look out for the following words and *ensure* you use them appropriately.

- Ensure
- Assure
- Verify

Verify that the content of the SOP is consistent with all supporting documents.

- Do the steps match between the procedure and any forms, checklists, or logs?
- If you are saying the same thing, do you say it the same way?
- Are all documentation requirements covered?
- Are signature/approval requirements explained and are they consistent between the SOP and the supporting documents?

Other considerations

- Is the content of the SOP free from any contradictions to existing policies or other procedures?
- Are all document titles listed correctly in the body of the SOP and in the References section?
- Are all documents listed in the References section described within the body of the SOP?

Procedural documents within an organization or across a network should be “branded” so that they look and feel similar.

- If properly branded, when staff members or research members see your policies, SOPs, forms, etc., they will be able to tell they are part of a “set.”
- **Some Common Branding Elements:**
 - Company or network logo
 - Standardized headers and footers
 - Standardized fonts
 - Standardized internal and external signature blocks
 - Standardized pagination
 - Dates in standard format
 - Document IDs
 - Document effective dates