UCLA SOPs

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Standard Operating Procedures

Standard Operating Procedures (SOPs) are uniformly written procedures, with detailed instructions to record routine operations, processes and practices followed within a business organization. In clinical research, SOPs help define the group's (e.g., unit, division, department, institution, etc.) standard practices and daily processes conducted to assure execution of research tasks in accordance with institutional, state and federal guidances.

SOPs should contain adequate detail to clearly guide research staff through a particular procedure and thereby establish uniformity in the everyday functions of the department. Each SOP should have a specific aim but be written in a general format that can be easily followed by a broad audience. By laying out defined processes, the primary function of an SOP is to specifically avert procedural deviations.

SOPs for the department should be written in a uniform manner. A standard format should be followed with consistent font size, unit title, and section headers. It should include page numbers, date of initial approval, date it was effective within the department and date of revision if applicable.

The key elements of the SOP at a minimum should include the objective of the SOP, definition of significant terms and acronyms, defined list of responsible individuals and details outlining the procedures with attachments of examples if applicable. It is important to reference applicable guidances and regulations within the SOP, such as ICH E6 Good Clinical Practice and 21 CFR 50. SOPs should be signed by the group's Administrator or Director, with the date of approval that signifies the SOPs are aligned with internal policies. Existing SOPs should be reviewed at regular intervals to reassess applicability of the policy. Annual review is recommended and review prior to sponsor interactions is encouraged.

Distribution, education and training on new departmental SOPs should be consistent. It is important to document the date research staff have been appropriately trained and are deemed competent to perform new SOPs implemented by the department. Research staff should be monitored consistently and receive refresher training at regular intervals to ensure compliance.

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SOP Guidelines for Writers

Basic SOP Guidelines for Writers

This document provides guidance for writing a standard operating procedure (SOP). These guidelines detail the type of

information to be included within each particular SOP section, along with writing dos and don'ts.

1. **Purpose**
   Explain the objective the SOP is intended to achieve.

2. **Scope**
   State the range of activities the SOP applies to, as well as any limitations or exceptions.

3. **Responsibility**
   State the personnel, departments, groups, contractors, and/or subcontractors responsible for both performing and complying with the SOP. State the person or group responsible for assuring the appropriate personnel are trained on the SOP.

4. **Procedure**
   Explain the procedure in simple steps. Carefully think about how a procedure is performed from the very beginning. Draft the SOP in a flow diagram to help visualize the entire process. Describe specifically what to do, not how to do it. Then state who does each step and where it is recorded to be certain that whoever is performing the procedure can prove that they have done it.

5. **Review and Revision**
   State how often the SOP is reviewed, and/or under what circumstances it is to be revised and indicate who is responsible for reviewing the SOP.

6. **Contingencies; Corrective Actions**
   State what happens if the SOP cannot be followed and requires contingencies. Identify who needs to be notified of contingencies and what documentation is required. Likewise, state what happens when an SOP is incorrectly followed. Include short term and long-term corrective action measures and how to document the actions.

7. **References**
   List related SOPs, any supporting documentation necessary to understand and correctly follow the procedure, and any applicable regulations and regulatory guidelines.

8. **Definitions**
   Define terms and acronyms that people reading the SOP would not generally know and that would require clarification. If a definition is needed, and one exists in the regulations, use the regulation definition.

9. **Documentation and Attachments**
   List applicable forms that are required to be completed in the SOP. Attach any documents used in support of the SOP, e.g., flowcharts, work instructions, pictures or diagrams, forms and labels.

10. **History of Change**
    A separate document should sufficiently detail changes made to an SOP, what parts were affected and when the changes become effective. Follow a uniform format for tracking SOP changes; indicate who made the revision, date of revision and the new version number. Properly archive an outgoing version and - all exisiting copies - to avoid unnecessary confusion.

11. **Content**
    Check the SOP to make sure it is clear, correct, concise, complete, and comprehensive. Use language and detail appropriate to the staff performing the task. Use short sentences to express a single thought wherever possible. Use techniques that condense information, e.g., tables, matrices, bulleted lists, checklists, and diagrams. Write the text in the third person, present tense, active voice. State in the procedure what is done, not what must, shall, or may be done. Avoid references to gender ("they, their" rather than "he, she"). Express the main idea early in each sentence. Define job titles or unusual terms the first time they appear, followed by

the abbreviation in parentheses. The abbreviated form is used in the SOP. Avoid the use of "etc." If the list is limited, write it out in full. If a list is extensive and inappropriate to write out in full, write the term "for example (e.g.)" and give a relevant list. Write the numbers 1 through 9 in words within the text. Write the numbers 10 and greater in the numerical form.

12. **Style**
    The page header should include the name of the Organization, address and if possible the department or group. The header will then include the SOP number, title, Version number, page number, and effective date. Often, the author's name of the SOP is in the header. At the end of the SOP, indicate a section for documenting SOP reviews with space for reviewer's signature and date signed. If the SOP is to archived or retired, add a line to document this purpose. The page footer should include the complete filename and path.

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- Sample SOP from UCSF
- UCLA Record Retention and Archiving SOP
- UCLA Form FDA 1572 SOP
- University of Michigan Sample SOPs (editable)
    - AE Reporting
    - Archiving Records
        - Archiving Records 2
        - Archiving Records 3
    - ClinicalTrials.Gov
    - Data Collection
        - Data Collectiion Appendix
    - Equipment/Instrumentation
        - Equipment/Instrumentation Appendix A
        - Equipment/Instrumentation Appendix B
    - FDA Inspections
    - Informed Consent
    - Internal QA
    - Investigational Products
    - IRB Submission
    - Monitor Audit Visits
    - Noncompliance
    - PI Oversight of Staff Roles
    - Protocol Development
        - Protocol Development Appendix A
    - Research Staff Training
    - Screening/Enrollment
    - SOP of SOP
        - SOP Appendix A
        - SOP Appendix B
        - SOP Appendix C
        - SOP Appendix D
        - SOP Appendix E

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SOP Resources

- Sample SOP from UCSF
- Basic SOP Guidelines for Writers
- SOP Examples from Duke University
- UCLA: SOP Template Library (Templates and library for common chemicals and chemical groups.)
- SOP Sample Table of Contents

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Drupal.jQueryUiFilter.globalOptions('accordion');