SOPs Overview

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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