



Developing a Site-specific SOP

Presented by: Janet Grab

When You Don't Know Where to Start



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SOP on SOPs



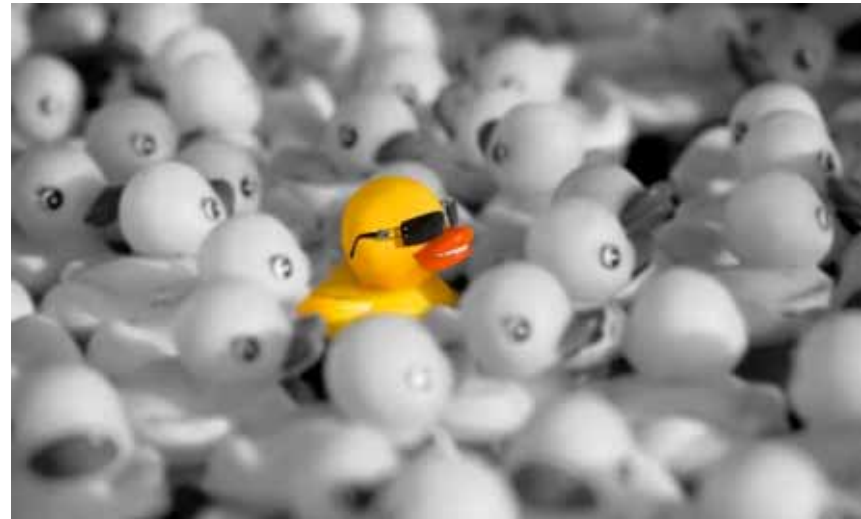
- WHO decides when a new SOP is needed
- WHO will draft the SOP
- WHO will approve it (PI)
- The layout of the SOP (SOP template as an appendix)
- Version control: numbering, superseded SOPs (stamped, archived)
- Document control: paper vs electronic
- Implementation, including training
- Maintenance: frequency of review



Site specific



- Unique
 - Type of trials
 - Therapeutic area
 - Expertise & Experience
 - Regulatory environment
 - Sponsor requirements
 - Staff complement
- Must be a right fit for your site!



Title & Signature Page



- Descriptive Title
- Issue date
- Effective date (after training has taken place)
- Review date
- Details of review & revisions – include a tracked changes version if there are extensive changes
- Signed off by Author and Appro

APPROVED

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Responsibilities



- WHO?
- Remember back up
- Use functional role descriptions, not names
- Anyone mentioned here must be trained



Procedures

- Must be doable
- “Hit by a bus” test
- Logical step-by step, short concise sentences
- Observe how things are currently done & documented
- Set the minimum standard
- “ Unless otherwise described in the Protocol...”





References

- Sources
- Regulatory framework documents
- Up-to-date versions of documents e.g. ICH-GCP, SA GCP, Declaration of Helsinki etc., are used.

Appendices

- Relevant forms, checklists, templates etc. to be used in implementation of the SOP
- Documents that need frequent updating

Training



CRS Leader/Principal Investigator	X
Sub-Investigators	X
<u>Programme Manager</u>	X
QA Manager	X
Internal QA Monitor	X
Regulatory Compliance Manager	
Regulatory Compliance Officer	
Pharmacist of Record	X
Back-up Pharmacists	X
QC Officers	X
<u>Study Co-ordinators</u>	X
Research Nurses	X
Research Counsellor	
Community Health Care Workers	
Research Study Assistants	
Field Workers	
Data Manager	X
Data Capturers	X



Training

- Training on a new SOP/revised version
 - Self training vs training presentations
 - Practical sessions
- Training new staff







**KEEP
CALM
AND
WRITE
SOPs**

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