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|  | **SOP Title:** Writing a Standard Operating Procedure (SOP) |
|  **Study title**: *Give study title to which this applies* |

# **Scope and application**

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| This procedure provides a guideline on how to write a Standard Operating Procedure (SOP), including how to format the document. The purpose of a SOP is to provide detailed instructions on how to carry out a task so that any team member can carry out the task correctly every time. The purpose or objective of a SOP should restate and expand a well-written title. A well-written SOP will facilitate training. The best SOP is one that accurately transfers the relevant information and facilitates compliance with reading and using the SOP. This SOP for SOPs is aimed at Work Package (WP) leaders, task leaders and all those who will be involved in SOP writing. It applies to SOPs developed within the ALERRT Work Package on DM/ICT. |

# **Responsibilities**

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| **Function** | **Activities** |
| SOP author | * Draft SOP in consultation with the intended users Correct SOP according to feedback
* Amend SOP if required
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| Team membersWP (Project) Lead and Co-lead  | * Review SOP initial draft and consecutive amendments Release and formally approve SOP versions
* Make SOP available through ALERRT website
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| QA managerMonitor | * Ensure compliance of SOP by all intended users
* Ensure the SOP version used is the most recent one approved by WP Lead/Co-lead
* Report non-compliance to PI and WP Lead/Co-lead
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# **Definitions**

**DM:** Data Management

**ICT:** Information and Communication Technology

**Form:** A form is a document which is to be printed at the time of use and filled out for the purpose of becoming a record (e.g. Library Log Form), or for the purpose of becoming Visual Display tool.

**Principal Investigator (PI):** A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

**Standard Operating Procedures (SOPs)**: Detailed, written instructions to achieve uniformity of the performance of a specific function.

**Template:** A template is a form to be used as a model for creating other documentation.

**Visual Display (VD):** A VD is a form requiring no additional data to be added, (i.e. no written record) which provides visual information to instruct in the process, e.g. “Out of Order” tag stuck on a machine. The information can be in the form of pictures or photographs; flowchart; operating instructions; or a notice. The Visual Display form is usually located in a permanent position, however maybe in use for a specific period of time, e.g. for a single batch. Pages from a single Visual Display form must be located together in a specified location.

**Work Package (WP):** Group of related tasks within a project. Within ALERRT: WP1 refers to “Clinical Research Platform”, WP2 refers to “Laboratory Research Platform”, WP3 refers to “ICT & Data Management”, WP4 refers to “Operational Readiness & Resilience”, WP5 refers to “Training and Capacity Building”, WP6 refers to “Impact” and WP7 refers to “Coordination & Management”.

# **Procedures**

## Writing a Standard Operating Procedure (SOP)

* Write one SOP per study or WP-related activity. Ex: Data entry, Testing of data management system, Coding of adverse events data etc. Do not mix too many activities in one SOP.
* Make sure you are familiar with the procedure to be described in the SOP. If you are not, ask somebody who performs the procedure regularly to show it to you. Have this person read/review your first draft before you send it to the WP Lead and Co-lead for review and approval.
* Describe in details how the procedure is being carried out.
* List the steps in a chronological order as in this example: Making a cup of tea:
1. Collect a cup and saucer
2. Place teabag into cup
3. Boil water in kettle
4. Add water to cup and teabag
5. Allow tea to infuse
6. Remove teabag
7. Add milk and sugar (if desired)
* Use a simple, active language e.g. ‘weigh 10 mg’ rather than ’10 mg should be weighed’.
* Indicate in the “Responsibilities” section who is doing what. Do not use people’s name, use functions/ job title/ study role e.g. laboratory technician, physician, data entry clerk…
* Include all necessary information to perform the procedure, not more.
* Use the fewest possible words, if different steps are involved in the activity, use bullet points.
* If possible add visual displays (VD) such as diagrams, flow charts, pictures or table.
* Have a specific reader in mind. Know the type of person who will be reading the procedure and tailor the writing according to the end user.
* Avoid “do this or alternatively do that”
* Avoid “where appropriate”
* Make sure all technical terms and acronyms are defined under the “Definition” section.

## SOP Format

* Use the SOP template attached to this SOP.
* Assign each SOP a unique identifier which includes:
	+ the number of the Work Package under which the SOP is being developed
	+ the number of the SOP: each new SOP within a certain WP gets a sequential SOP number within each WP
	+ short term description referring to the type of the procedure (SOP on SOP, data entry, system validation,…
	+ version number of the SOP (e.g. 0.1 for first draft, 0.2…1.1, 1.2… for revision or amendment, …1.0, 2.0… for final versions
	+ language of the SOP (FR = French, EN= English, see also 4.4)
	+ version date of the SOP: relates to the date a revised version or final version or translated version was finalized.



* If the procedure is a lengthy one, then the description of the procedure can be split up and placed under smaller headings. e.g. ‘3.1 Data collection, 3.2 Data entry, 3.2.1 Double data entry, 3.2.2 Single data entry , …’
* Indicate on each page of the SOP:
	+ The SOP number, the version number, language acronym and version date
	+ The page number and the total number of pages

## SOPs review and version control

* The author of a SOP will sent out the SOP as a draft for contributions/review to WP Lead, Co-lead or team members. The first draft should be circulated as version 0.1. Contributions, comments and corrections should be incorporated in this draft . Various drafts 0.2, 0.3 … may be distributed as such to create a final version 1.0. Only final versions need to be listed in the Document History table.
* WP Lead and Co-lead are responsible for the final approval (final OK) of each SOP. If the WP Lead is author, then only the Co-lead will approve (and reverse).
* The SOP should be signed by the SOP author and by the WP Lead and Co-lead who approve it.
* Corrections and amendments of version 1.0 should also be submitted for review to the WP Lead or Co-lead or a team member. Version 2.0 should be created only after final approval of WP Lead and Co-lead has been obtained.
* Each consecutive version and reason for modification made to the SOP should appear in the “Document History” section at the end of the SOP.

## SOPs language

* Provide SOPs in English and French. For reasons of convenience, SOPs might be written first in English and translated at a later time in French (or the reverse).

## SOPs management

* Keep your SOPs adhered to this SOP on SOP.
* Provide a log within your WP with all the SOPs produced by your WP team members (e.g; excel sheet listing up all your WP produced SOPs, with reference to language and approved versions). See example in Attachment 02.

# **Attachments**

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| **Attachments** |
| **Number** | **Title** |
| 01 | Template SOP on SOP-English version |
| 02 | ALERRT SOPs and documents tracker |
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# **Document History and References**

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| **Revision**  |
| **Version number** | **Author** | **Date** | **Description/reason for modification** |
| 1.0 | Harry van Loen | 02/10/2019 | Initial version - Based on SOP\_WP6-QUAL-01\_V1\_02Nov2011 (see FP 7 European funded project NIDIAG with Project ID: 260260).Review by Fatoumatta Cole, Hanne Landuyt and Yusupha Njie.Approval by Bai Lamin Dondeh. |
| 2.0 | Harry van Loen | 17/06/2022 | Review to ensure that the SOP is appropriate within ALERRT and with current clinical research best pratices. |

# **Approval**

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| **Name and function** | **Date (dd/mm/yyyy)** | **Signature** |
| ***Author*** |
| *Indicate who wrote the SOP* |  |  |
| ***Review*** |
| *Indicate WP team members who reviewed (if applicable)* | *Date of review* |  |
| ***Approval*** |
| *Indicate WP Lead/Co-lead(s) who approved* | *Date of approval* |  |