1. Contributors to this SOP

| Adopted by | International Regional Team Leader (IRTL) | Jalal Jebelli |

2. Recommended venues for the utilization of this SOP

<table>
<thead>
<tr>
<th>Item</th>
<th>Utilization</th>
<th>Institution</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Internal utilization by experts and supporting staff</td>
<td>SMIS Project Mekele, Tigray</td>
</tr>
</tbody>
</table>

3. List of Standard Acronyms & Definitions

**SOP** Standard Operating Procedure

**FAM** Financial and Administration Manager

**FO** Financial Office

**AO** Administrative Officer

**NRTL** National Regional Team Leader

**IRTL** International Regional Team Leader

**AWP** Annual Work Plan

**Controlled document:** Has an identification number or a unique title, a version number, Documentation: All records technical reports, progress reports (monthly, quarterly, semi-annual, annual, occasional), field visit reports, assessment reports, validation reports, etc...

**Forms:** Controlled document standardizing the recording of information for activity\sub-activity copied on: e:\Tigray-server\Z:\QA\Forms\

**Memos:** A document that may be related to a SOP indicating dynamic information, which may require regular updating.

**Position Papers:** A written report of intentions.

**Standard operating procedure (SOP):** Standardize way to perform activities/sub-activities.
4. **Purpose**

The purpose of this Standard Operating Procedure (SOP) is to provide to all employees Good Documentation Practices (GDP) requirements.

5. **Responsibilities**

The responsible parties for implementation of this SOP are:

- Financial and Administrative Manager (FAM),
- Administrative Officer (AO),
- Employees,
- Team Leader (NRTL/IRTL).

5.1 In the absence of Quality Assurance Manager, the Financial and Administrative Manager (FAM) is charged to this task and will be responsible to:

5.1.1 Perform reviews to ensure that:

5.1.1.1 Employees are trained on this Good Documentation Practices,
5.1.1.2 Employees are documenting according to the SMIS Project Quality System and GDP requirements,
5.1.1.3 Documentation is current, accurate, signed, dated and archived properly,
5.1.1.4 Identifying problems regarding non-compliance with Good Documentation Practices,
5.1.1.5 Identified problems or proposals are documented and that the proposed actions have been implemented,

5.1.2 Create and maintain the Quality Document Index indicating document reference, title and issue status in relation to the SMIS Project Quality System,

5.1.3 Maintain version control and change history for controlled documents including identifying versions as “drafts”, “approved”, “effective”, “implemented” and “obsolete”.

5.2 Administrative Officer (AO) is responsible to:

5.2.1 To assist the FAM to implement correctly this SOP,
5.2.2 To maintain the hard and softcopy of this SOP on server,
5.2.3 To report any non-compliance to FAM.

5.3 Employees are responsible to:

5.3.1 Follow Good Documentation Practices in:

5.3.1.1 Completing documents including technical reports, progress reports (monthly, quarterly, semi-annual, annual, occasional), field visit reports, assessment reports, validation reports, etc.,
5.3.1.2 Labeling, signing and dating documents appropriately.
5.4 Team Leader (NRTL/IRTL) is responsible to:
   5.4.1 To control and to provide oversight to improve the implementation of this SOP,
   5.4.2 To verify and to approve this SOP and any subsequent changes.

6. Procedure
   6.1 Documents in general should have the following characteristics:
     6.1.1 Be written according to the SMIS Project style guide,
     6.1.2 Has accurate data,
     6.1.3 Factual: meaning that what is written is what is intended to happen or actually happened,
     6.1.4 Does not include pre or post-dating,
     6.1.5 Completed at the time of occurrence,
     6.1.6 The IRTL/NRTL approves it or in some circumstances has at least the verbal endorsement of IRTL/NRTL,
     6.1.7 Prepared with consistent format and layout as follows:
       6.1.7.1 Headers and footers contain the following as required:
           • SMIS Project logo,
           • Document title,
           • Type of document (i.e. draft, final report etc.),
           • Document number,
           • Version number,
           • Page number of total number of pages (page x of y),
           • Confidentiality statement if necessary,
           • Copyright information.
     6.1.8 Labeled: starting with general description and ending with specific topic,
     6.1.9 Archive information for archiving a hard and soft copy,
     6.1.10 A hard copy of the final product (signed and dated) which has a soft copy on a CD attached at the end of document goes to archive.
     6.1.11 Versioned:
           • Drafts are numbered as v1.1, v1.2, v1.3, etc..., 
           • First draft sent for PI review is version v2.0,
           • Changes to the first version v2.0 begin as draft v2.1, v2.2, etc.,
           • Second draft sent for PI review is version v3.0,
           • Final APPROVED version is the last version number.

7. Availability:
   7.1 This SOPs is available for use on the server as PDF file at e\Tigray-server\Z:\QA\SOPs\ 
   7.2 Current original hard copy versions of SOP is maintained in archive in the Quality Assurance binder.

8. Completion
   8.1 Dates: are recorded as “dd mmm yyyy” two (2) digits for the date, first three (3)
characters for the month and four (4) digits for the year (i.e. 07JUL2014). Full dates are acceptable “mmmm, dd, yyyy” (i.e. JULY07, 2014).

8.2 Approved documents/forms only are used for entering information. If non-approved documents/forms are used (i.e. scrap paper, “stickers”), they are attached to the approved document, referenced accordingly and noted as a deviation.

8.3 Transcription of data/information is forbidden unless is accompanied by original date/information and identified as such (i.e. transcribed from document “x”).

8.4 Time is recorded as per the 24 hour clock, HH:MM (i.e. 17:00).

8.5 Decimals are rounded up from 5 and down from 4.

8.6 Units are recorded according to the study specific requirements indicated in a study specific memo as per SOP of Quality Documents.

8.7 Blank spaces are crossed out when there is a prompt for information, which is not provided and labelled “N/A” for not applicable.

8.8 The author completes, signs INITIALS and dates the original document for archive.

9. Record of significant changes

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<thead>
<tr>
<th>Version Number</th>
<th>Section Changed</th>
<th>Reason for change</th>
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