


Omni Healthcare Communications



STANDARD OPERATING PROCEDURE

TITLE:	Establishment of Standard Operating Procedures	SOP #:	OMN-100.00
DEPT:	Quality Assurance	REVISION #:	1
PREPARED BY:	Stephen M Casey	EFFECTIVE DATE:	04/19/2019
APPROVED BY:	Stephen M Casey, Managing Partner		Page 1 of 2
SIGNATURE:		SIGNATURE DATE	04/19/2019

1.0 Purpose

1.1 To describe the process for the development, review, and training for Sunny Ayr Holdings Ltd (SAH) and all its affiliate company's Standard Operating Procedures (SOPs).

2.0 Scope

2.1 These procedures apply to all of SAH's service providers including; any employees, consultants, and contractors participating in services or other efforts managed by SAH for a client.

3.0 References

3.1 Including but not limited to:

- United States Federal Food and Drug Administration Regulations (FDA)
- The Open Payments Law at Section 6002 of the Patient Protection and Affordable Care Act (Public law No. 111-148) and all regulations promulgated thereunder (42 C.F.R. part 403, subpart 1)
- International Conference on Harmonization Guidelines E6: Good Clinical Practice – a Consolidated Guidance

4.0 Definitions

4.1 SOP – Standard Operating Policy and/or Procedure.

4.2 Authorized Designee – may include employees of SAH, consultants, subcontractors, and/or a Contract Research Organization.

4.3 CRO: Contract Research Organization

5.0 Responsibility

5.1 SAH is responsible for ensuring that this documented quality system is in accordance with appropriate standards and regulations. The author of an SOP, as designated by the Managing Partner (MP) or the Managing Executive (ME), is responsible for ensuring that Standard Operating Procedures adhere to the approved format.

5.2 The MP or authorized designee is responsible for ensuring that SOPs are reviewed and approved on an annual basis. In addition, the MP or authorized designee may initiate the review and approval process on an expedited basis for specific SOPs at the request of SAH employees, contractors, vendors or other authorized designees when it is determined that clarification or modification to existing SOPs are required in order to ensure compliance with current Good Practice Guidelines.

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- 5.3 The MP, or authorized designee, is responsible for ensuring that all sub-contractors to whom SAH has transferred any of client's responsibilities maintain Standard Operating Procedures (SOPs) consistent with regulations and guidelines.
- 5.4 The MP or authorized designee, is responsible for certifying that all employees, consultants, and contractors receive adequate training with regard to their respective duties stipulated within applicable SOPs.

6.0 Procedure

6.1 This SOP provides the instructions, and serves an example, for the format to use for all SOPs prepared for the SAH team.

- The font used for the body of the document is 10-point "Arial."
- The headers and footers are formatted at 0.5" from the top and bottom of the page, respectively. The page one header includes the SAH logo, the title "STANDARD OPERATING PROCEDURE", and the following information:
 - Title of the SOP: the complete title of the SOP
 - SOP #: SOP numbers are assigned by the MP, or authorized designee, in keeping with a hierarchal order associated with the functional area governed by the SOP
 - Dept. name: will be Quality Assurance, unless directed otherwise
 - Revision #: SOPs approved for the first time are indicated as "0." Subsequent revisions will be indicated as: "01, 02, 03" etc.
 - Prepared by: the primary author responsible for drafting the current version of the SOP
 - Approved by: the MP, unless directed otherwise
 - Effective date: indicates the date the SOP is scheduled to go into effect which will not precede the signature date of the individual authorized to approve the SOP
 - Signature and date approved by the primary author
 - Signature and date of the individual authorized to approve the specific SOP
 - Page number(s)
- Footers on all pages will contain the following information:
- Typedate: 04/19/2019 SAH-100.00 SOP Umbrella 4-19-2019