STANDARD OPERATING PROCEDURE

TITLE:	Format for Standard Operating Procedures	SOP #:	OMN-101.00
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 3
SIGNATURE:		SIGNATURE DATE	04/19/2019

1.0 Purpose

To describe the format specifications to use for the Standard Operating Procedures (SOPs) for the Sunny Ayr Holdings (SAH) and all its affiliate company's.

2.0 Scope

All SOPs created for the Department of Clinical Development at SAH will follow the format specified herein.

3.0 References

ICH Guideline E6: Good Clinical Practice – a Consolidated Guidance

4.0 Definitions

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

5.0 Responsibilities

The Managing Partner (MP), or authorized designee, is responsible for ensuring that Standard Operating Procedures adhere to the approved format.

6.0 Procedures

This SOP provides the instructions, and serves an example, for the format to use for all SOPs prepared for the Department of Clinical Development at SAH Technologies. The font used for the body of the document is 10-point "Arial", and the text is single-spaced with 6-point spacing following each paragraph. The margins are set to occur at: 0.69" (top); 1.0" (bottom); 0.89" (left); and 0.63" (right). The headers and footers are formatted at 0.5" from the top and bottom of the page, respectively. The American Medical Association Manual of Style will be used as a guide for the rules of grammar, punctuation, capitalization, abbreviations, etc.

6.1 The page one header includes the SAH logo, the title "STANDARD OPERATING PROCEDURE", and the following information using the 9-point "Franklin Gothic Book" font:

- 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 Clinical 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 CEO, 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)

6.2 As illustrated above, the headers following page one are essentially identical to that of page one, except that only the initials of the primary author and the individual authorized to approve the SOP are required, and the primary author's name is eliminated.

6.3 Footers on all pages will contain the following information:

- "CONFIDENTIAL INFORMATION: DO NOT DISCLOSE WITHOUT PROPER AUTHORIZATION" centered in 10-point "Arial" font
- Type date: the date the particular draft version is prepared (flushed left in 8-point "Arial" font)
- The electronic file name (i.e., path directory) corresponding to the location of the SOP document (flushed right in 8-point "Arial" font)

6.4 The primary sections of each SOP (i.e. the "first-order" headings) are flushed left, **bolded** and include:

- **Section 1.0: Purpose** – a brief description of the objective(s) for the specific SOP. If the SOP addresses more than one objective, they may be numbered 1.1, 1.2, etc.
- **Section 2.0: Scope** – an overview of the procedures encompassed within the specific SOP, e.g., the clinical development stage(s) addressed by the SOP, and/or the individuals, departments, and organizations affected by the SOP. If the scope of the SOP involves more than one distinct stage, each stage may be numbered 2.1, 2.2, etc. Detailed lists incorporated within the Scope will be "bullet-pointed."
- **Section 3.0: References** – includes the number and title of federal and local regulations, and/or federal and international regulatory guidelines associated with the procedures described in the specific SOP.
- **Section 4.0: Responsibilities** – identifies the primary individuals (by the title of their positions at SAH and/or authorized vendors and organizations) who are responsible for carrying-out the described procedures
- **Section 5.0: Definitions** – terms used within the specific SOP that warrant clarification. The term being defined is underlined.
- **Section 6.0: Procedures** – If applicable, the procedures section may include an introductory paragraph (which is not numbered) that applies to the entire section. (See example paragraph following section 6.0 of this SOP.)
  - Distinct stages of the tasks encompassed by the SOP (i.e., "second-order" headings) will be numbered 6.1, 6.2, and 6.3, etc. and will be indented 0.5 inch from the left margin.
  - Sub-sections: the detailed tasks associated with each stage of an SOP (i.e., "third-order" headings) will be numbered 6.1.1, 6.1.2, and 6.1.3, etc. and will be indented 1.0 inch from the left margin.

  - Lists: detailed lists of items, which may occur either within second or third-order sections, are “bullet-pointed” and will be indented and additional 0.25 inch from either the second or third-order heading. A list of items following a bullet-point item will be preceded by a “dash-point” and will be indented an additional 0.25 inch from the bullet-point setting.

- **Appendices:** examples of commonly used forms, checklists, contracts, etc. will be appended to the SOP manual rather than incorporated within specific SOPs. In general, the samples provided will serve as a guideline and may be replaced by similar documents as authorized by the individuals responsible for the primary procedures described in the specific SOP.