


Omni Healthcare Communications



STANDARD OPERATING PROCEDURE

TITLE:	Project Naming and Numbering	SOP #:	OMN-104.00
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 naming projects for Sunny Ayr Holdings Ltd and all its company's (SAH) on the project naming protocol.

2.0 Scope

2.1 These procedures apply to all 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

4.4 Electronic Files – any document, spreadsheet, audio file, video file, data file, powerpoint file, or other form of electronic file required for use in a project.

4.5 Project – an individual or collaborative enterprise that is carefully planned and designed to achieve a particular aim for an SAH client.

4.6 Share – actively sending an electronic file link or hard copy of a file to another person.

4.7 Site – A page or series of web pages having a pre-defined location with the SAH SharePoint system and dedicated to contain content for a specific Client or Project.

4.8 Time Tracker: Time tracking software designated by SAH for the use of authorized designees to record and submit their time for activity they have undertaken in conjunction with a project

4.9 Affiliated Company(s) – Omni Healthcare Communications LLC, Ascendant Limited, and/or eCTD Solutions Ltd

Omni Healthcare Communications LLC			
TITLE:	Project Naming and Numbering	SOP #:	OMN-104.00
DEPT:	Quality Assurance	REVISION #:	1
EFFECTIVE DATE:	04/19/2019	Page 2 of 2	

4.10 Accounting Program: Accounting software designated by SAH for the use of authorized designees to record and submit revenue and expenses of the company.

4.11 Office 365: Productivity software allowing for sharing and storage of documents among team/group members

5.0 Responsibility

5.1 SAH is responsible for ensuring that this naming protocol/system is in accordance with appropriate standards and regulations. The authorized designee, as Identified by the Managing Partner or the Managing Executive (MP) of each specific operating company, is responsible for ensuring that this SOP is adhered with and adheres to the approved SOP format.

5.2 The MP or authorized designee is responsible for ensuring that the full naming protocol SOP is reviewed and approved on an annual basis.

5.3 The MP or authorized designee, is responsible for certifying that all employees, consultants, and contractors receive adequate training regarding their respective duties stipulated within this SOP.

6.0 Procedure

6.1 This SOP provides instructions, and serves an example, for the format to use for all Projects as they are created and set up in SAH processes, software programs, and communications.

6.2 All Projects undertaken by SAH will be set up in the Time Tracking, Accounting Program, and Office 365 software with a defined naming protocol:

- A base of 9 characters to comprise the main Project name
 - Characters 1-3 will identify the Client name
 - Characters 1-3 will be the first two characters of the Client name
 - Characters 4-5 will identify the year of Project initiation
 - The year will be identified using the last 2 digits of the year the Project SOW was fully executed.
 - Characters 6-8 will identify the Client Project number
 - Character 6 will identify the division/company that the project is being conducted in. A "1" will be used to designate a project being conducted in SAH.
 - Character 7-8 will be a sequential number to identify the main Project (eg. 01, 02, 03).
 - Characters 9 and beyond will identify the subproject, if any, of the main Project (eg. A Publication Plan Project will have subprojects of publications, etc)
 - The product the project is being conducted for will be identified by using the first 4 characters of the Client product name.

6.3 Project numbering will be used to identify the Projects across all SAH operations.

6.4 Project Numbering will be used when adding Project sites to Client sites on the SAH SharePoint system

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