

# Omni Healthcare Communications



## STANDARD OPERATING PROCEDURE

TITLE:	Creation of SharePoint Sites	SOP #:	OMN-105.00
DEPT:	Quality Assurance	REVISION #:	1
PREPARED BY:	Stephen M Casey	EFFECTIVE DATE:	04/19/2019
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SIGNATURE:		SIGNATURE DATE	04/19/2019

### 1.0 Purpose

1.1 To describe the process for the development, naming, and storage for Sunny Ayr Holdings Ltd and its affiliated companies (SAH) generated and received electronic files.

### 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 Definitions

- 3.1 SOP – Standard Operating Policy and/or Procedure.
- 3.2 Authorized Designee – may include employees of SAH, consultants, subcontractors, and/or a Contract Research Organization.
- 3.3 CRO: Contract Research Organization
- 3.4 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.
- 3.5 Hardcopy Files – any document, spreadsheet, data listing, powerpoint file, or other form of paper file required for use in a project.
- 3.6 Project – an individual or collaborative enterprise that is carefully planned and designed to achieve a particular aim for an SAH client.
- 3.7 Office 365 environment – Office 365 is an online integrated experience of apps and services, designed to facilitate business collaboration. The environment is accessible through a portal using any internet browser. It can be accessed through any device capable of accessing the internet. It can also allow advanced users to create native applications on devices so the user experience does not require sign in to the portal all the time.
- 3.7 SharePoint – a web-based collaborative platform within SAH's Office 365 environment that integrates with Microsoft Office applications. Primarily used as document storage and management system.
- 3.8 Nested Site – a SharePoint site constructed of 1 parent (Client) site and 1 or more child (Project) sites.
  - 3.8.1 Project site – a SharePoint site constructed under a Client site. These sites are only used for internal purposes and not shared outside of SAH.
  - 3.8.2 Client site – a SharePoint site set up as the parent to any project authorized and undertaken by SAH. These sites are shared with the clients and approved external personnel.
- 3.9 Share – actively sending an electronic file link or hard copy of a file to another person.
- 3.10 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.

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

3.12 Library – A file storage area located on the SharePoint system inside a specific site

#### 4.0 Responsibility

- 4.1 All SAH personnel and subcontractors will follow the procedures and guidelines presented in this document.
- 4.2 The Managing Partner or Managing Executive (MP) of each SAH specific affiliated company, or authorized designee, will be responsible for updating and maintaining this SOP.
- 4.3 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.

#### 5.0 SharePoint Site Creation and Naming Procedures

- 5.1 Each SAH operating company's Office 365 SharePoint System will be comprised of Project sites
  - 5.1.1 The MP, or authorized designee, will create SharePoint Sites for each project advanced by the SAH operating company.
  - 5.1.2 In the case where there is a direct Client associated with the Project and Client approval is required for completion or payment on a Project a Client site will also be created and the Project Site will be a "child site" to the Client site or a Nested SharePoint site.
  - 5.1.4 Client sites will use the Client name to identify the site while each project will be identified by its Project Name as identified in SAH SOP 104
- 5.2 The Client site and Project site will define the level of permission and access for the project
  - 5.1.5 The project Medical Writer and Project Manager will be designated as "owners" on Project Sites
  - 5.1.6 After a Project site is completed the MP, or authorized designee, will share the site to team members that have been identified
  - 5.1.7 Clients will be given access to the Client site only. The MP, or authorized designee, will ensure that Project sites are given different sharing permissions to limit Project site access to internal SAH operating company team members

#### 6.0 Nested Site Shared Library's

- 6.1 To facilitate collaboration, document security, and proper archiving of all SAH work all electronic and hardcopy files will be stored using SAH's SharePoint system,
  - 6.1.1 Hardcopy files will be scanned and saved as PDF's on SAH's SharePoint system
- 6.2 When a Nested SharePoint Site is constructed or a Project site is added to a Client site, three library folders will be constructed for sharing across the Client and Project sites:
  - 6.3.1 Shared Folders will be identified by two asterisks ("\*\*") prior to the name
  - 6.3.2 Client Supplied Documents – this library folder is for the storage and sharing of electronic files that have been received by the client (eg, references, data files, etc).
    - 6.3.2.1 The Project Manager will be responsible for the folder design, file upload and curation of all client supplied electronic files.

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6.3.2.2 The Project Manager will be responsible for ensuring that all Hardcopy files supplied or developed in the process of the Project will be scanned and converted to PDF files for storage as an electronic file

6.3.2.3 If files available in the Client Supplied Documents library should not be moved, removed or shared with any other external personnel or resource other than Client personnel.

6.3.2.4 If files in this library are needed for publication through an external resource, they should be copied to an alternative location within the Client Site for sharing with the external resource.

6.3.2.4.1 Project Managers will be responsible for the creation of an alternative location to house a copy of the file

6.3.2.5 If an electronic file is an audio file or video file it may become necessary to move that file from the "Client Supplied Documents" library folder to a separate new library folder specifically configured for media files. In this extraordinary case the Project Manager will request this change from the Operations Manager.

6.3.3 Resources / References – This library folder is for the storage and sharing of documents that are used as references or resources in the development of SAH created documents/deliverables.

6.3.3.1 If files in this library are needed for publication through an external resource, they should be copied to an alternative location within the Client Site for sharing with the external resource.

6.3.3.1.1 Project Managers will be responsible for the creation of an alternative location to house a copy of the file

6.3.3.2 If an electronic file is an audio file or video file it may become necessary to move that file from the "Client Supplied Documents" library folder to a separate new library folder specifically configured for media files. In this extraordinary case the Project Manager will request this change from the Operations Manager.

6.3.4 Documents for Client Review – This library folder is for the storage and sharing of draft and final documents/deliverables developed by SAH for the Client.

6.3.4.1 The Project Manager will be responsible for the file design, upload and curation of all client supplied electronic files.

6.3.4.2 When the Project Manager has copied an electronic file/deliverable into this Library Folder he/she will share the completion of the file via email with a notification in the email that they will be receiving an Approval request generated from SharePoint that will allow them to click a response of either "approval" or "rejection" of the deliverable. Using the response system automatically adjusts the detail information in the library folder to show the file/deliverable has either been rejected or approved.

6.3.4.2 Files available in this library folder should not be moved, removed or shared with any other external personnel or resource other than Client personnel.

6.3.4.3 If files in this library are needed for publication through an external resource, they should be copied to an alternative location within the Client Site for sharing with the external resource.

6.3.4.3.1 Project Managers will be responsible for the creation of an alternative location to house a copy of the file

6.3.4.4 If files in this library are needed for sharing with the internal team, the Project Manager will be responsible for copying the file back over to a working library folder within a project site and sharing the file through the SharePoint sharing function with the other internal team members.

6.3.4.5 If an electronic file is an audio file or video file it may become necessary to move that file from the "Client Supplied Documents" library folder to a separate new library folder specifically configured for media files. In this extraordinary case the Project Manager will request this change from the Operations Manager.