


Omni Healthcare Communications



STANDARD OPERATING PROCEDURE

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|--------------|---|-----------------|-------------|
| TITLE: | Proper Use of SharePoint Sites | SOP #: | OMN-106.00 |
| DEPT: | Quality Assurance | REVISION #: | 1 |
| PREPARED BY: | Stephen M Casey | EFFECTIVE DATE: | 06/25/2019 |
| APPROVED BY: | Stephen M Casey, Managing Partner | | Page 1 of 4 |
| SIGNATURE: |  | SIGNATURE DATE | 06/25/2019 |

1.0 Purpose

- 1.1 To describe the process for the usage and standardization of SharePoint sites for Sunny Ayr Holdings Ltd and its affiliated companies (SAH)

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. For more on proper configuration of SharePoint, please see associated SAH SOP 105.
- 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.

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

- 5.1 An appropriate SAH Nested SharePoint site will be constructed in accordance with SAH SOP 105.
- 5.2 Electronic files will be stored on SAH's SharePoint, to facilitate collaboration, document security, and proper archiving of all SAH work
- 5.3 All any employees, consultants, and contractors will use the SAH affiliated company SharePoint System.

6.0 File Creation, editing, review and storage

- 6.1 Either the Project Medical Writer or the Project Manager will be responsible for the structure and naming of libraries, folders and files with a Project site.
- 6.1.1 Structure and naming responsibility will be determined by the Medical Writer at the beginning of the project.
- 6.2 Team members will access, create, edit, review, and store all work on SharePoint within the Office 365 environment through the portal.
- 6.2.1 Creation of work off-line and uploading it to SharePoint is not permitted and leads to errors.
- 6.3 Once named under the naming protocol, files will not be re-named, deleted, or copied without the permission of the Medical Writer.
- 6.4 To make edits or changes to an existing document, team members will use the word online application.
- 6.4.1 In the special case a team member needs to use more advanced capabilities not available in MS word online, they will first "sync" the parent folder with their device and then use the "edit in Word" button to open the document in their Word application on their device.
- 6.5 All files will be stored in a SharePoint location, within the Office 365 virtual server environment.
- 6.5.1 Internal files will not be shared outside of the internal team.
- 6.5.2 Permission changes to files or SharePoint folders, libraries, sites, etc. will be made by the Operations Manager.

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6.5.3 Finished or approved copies of files may be shared with the client through shared folders (please see SAH SOP 105 for more information)

7.0 File Naming Procedures

7.1 When saving files to a SharePoint site, library, folder, etc., all personnel including subcontractors will follow the naming conventions to simplify the process of finding files of certain types across different SharePoint sites and affiliated companies.

7.1.1 To prevent duplication of effort and maintain proper retention/archiving all files will follow:

SAH File Naming Convention (for all files created by SAH created files not directly involved in a Clients standard publication process that uses email with external authors)

- Files will not exceed 250 characters in length.
- The first three (1-3) characters will be the first three characters of the Client name.
- The next two (4-5) characters will designate the year of file creation (eg. 19, 20, etc)
- The next five (6-10) characters will designate "DRAFT" or "FINAL"
- If the file is a second, third, fourth or even higher draft the characters immediately following "DRAFT" (11-12) will be a dash and the number corresponding with the round of draft revision (eg. 2, 3, 4, etc)
- Characters 13-245 will be a description of the file

7.2 After each stage of development and review, a new folder will be created and the file should be renamed with an updated draft version number (Draft2, Draft3, Final, etc).

8.0 Team Member File Creation Procedures

8.1 In the instance where a team member other than the Medical Writer or Project Manager creates a file they may create the original file on their own device and upload it up to the proper designated folder as directed by the Project Manager.

8.2 After initial creation of the file the team member will access it through SAH SharePoint System.

8.3 Team members will use either the upload button within the proper SharePoint folder or drag and drop the file from the team members device storage

8.4 Team members will use the "Share" button on the Office 365 SharePoint folder menu to notify all other team members that the files have been added to the site.

8.4.1 In the case of adding multiple files to a SharePoint site, the team member may choose to identify all files via one notification instead of sharing each individual one

8.5 Team members working with SharePoint files should not create library folders, or other folders without discussing with the Project Manager

9.0 File Version Control Procedures

9.1 Version control will be managed by both the Medical Writer and the Project Manager.

9.2 Using version control is required by all team members

9.3 Version control is the default setting in the SAH SharePoint system.

9.3.1 Version control will not be turned off

9.3.2 Once a file is created the name should not be changed. All changes to the file should be saved over the top of the old file. (Office 365's SharePoint will automatically save a version as well as specifics about the new version.

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9.3.3 Older versions of a file may be accessed through the document menu on SharePoint

9.4 To ensure version control all team members will always open documents from SharePoint.

9.5 After each session team members will save the file over the top of the old file and close out the browser window.

9.6 Before taking a break, team members will save their work and close out the browser window.

9.7 If a session is interrupted the team member will save the work after the interruption

9.3.1.1 In some instances it may be hard to identify a save button in this instance the team member will close out the open file browser window which will automatically save it.