


# Omni Healthcare Communications



## STANDARD OPERATING PROCEDURE

TITLE:	Standard Operating Procedures Training Certification	SOP #:	OMN-103.00
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 by which employees, consultants, and contractors of Sunny Ayr Holdings and all its companies (SAH) will receive training with regard to their respective duties delineated within Clinical Development Standard Operating Procedures (SOPs).

### 2.0 Scope

- 2.1 These procedures apply to all of SAH's employees, consultants, and contractors participating in Client work

### 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 Project – a properly authorized work/job for a client or a potential client.

### 4.0 Responsibility

- 4.1 All SAH personnel and subcontractors will follow the procedures and guidelines presented in this document.
- 4.2 The SAH Managing Partner (MP), 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 with regard to their respective duties stipulated within applicable SOPs.

### 5.0 Outline

- 5.1 The MP, or authorized designee, will ensure that all employees, consultants, and contractors under direct supervision of SAH will have access to a complete set of updated SOPs, and a certification form for each individual recipient to indicate that they have received, read, and understood the policies and procedures described therein.
- 5.2 The MP, or authorized designee, may conduct specialized training sessions with regard to selected sets of SOPs on a periodic basis as warranted. These specialized training sessions, scheduled to occur at appropriate intervals, may include but are not limited to the following:
  - New employees, contractors, or consultants have been hired
  - Significant changes to existing SOPs have occurred
  - New SOPs have been approved
  - At the request of employees, consultants, or contractors when clarification of SOPs is sought
- 5.3 The MP, or authorized designee, will verify that all organizations to whom SAH has transferred any of Client's obligations maintain training records for all personnel responsible for carrying-out Client required responsibilities.

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5.4 The MP, or authorized designee, will retain copies of training session attendance records and certifications in accordance with ICH guidelines.