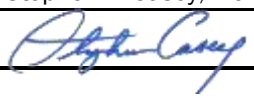
Omni Healthcare Communications

STANDARD OPERATING PROCEDURE

TITLE:	Revision of Standard Operating Procedures	SOP #:	OMN-102.00
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 process whereby Sunny Ayr Holdings Ltd (SAH) Standard Operating Procedures (SOPs) are periodically reviewed and revised as warranted.

2.0 Scope

Clinical development SOPs will be maintained and updated as warranted for Phase II – IV clinical trials sponsored by SAH Technologies.

3.0 References

International Conference on Harmonization (ICH) Guidelines

United States Federal Food and Drug Administration (FDA) Regulations

Health Canada's Therapeutic Products Programme (TPP)

4.0 Definitions

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

SOPs – Standard Operating Procedures

5.0 Responsibilities

The Manager, Quality Assurance, or authorized designee is responsible for ensuring that SOPs are reviewed and approved on an annual basis. In addition, the Manager, Quality Assurance, or authorized designee may initiate the review and approval process on an expedited basis for specific SOPs at the request of SAH employees, contractors, vendors or other authorized designees when it is determined that clarification or modification to existing SOPs are required in order to ensure compliance with Good Clinical Practice Guidelines.

6.0 Procedures

6.1 Annual Reviews

The Manager, Quality Assurance, or authorized designee will initiate the SOP review and approval process on an annual basis (or more frequently if warranted) for all clinical development procedures that have been in effect for at least one year's duration.

6.1.1 The Manager, Quality Assurance, or authorized designee will conduct periodic reviews of materials available from FDA, ICH and other relevant governing authorities to determine if new or revised regulations or guidances have been published that would potentially impact the clinical development procedures currently in place.

6.1.2 Based on a review of the literature, requests for revisions, and comments received from SAH employees, contractors, and other authorized designees, the Manager, Quality Assurance, or authorized designee, will determine if revisions are required for existing SOPs under review.

6.1.3 The Manager, Quality Assurance, or authorized designee, will draft revised SOPs, if warranted, corresponding to each SOP under review. If no revisions appear to be required, the existing SOP will be circulated for review and re-approval as stipulated below.

6.1.4 At the discretion of the Manager, Quality Assurance, or authorized designee, copies of relevant publications, in whole or in part, or summaries thereof may be provided to accompany the draft SOPs under review.

6.1.5 Copies of draft SOPs review, and any relevant accompanying materials, will be circulated to designated staff members for review and approval. An SOP Review Routing Form [see Appendices] will be attached to each SOP which provides for the following:

- A heading indicating the review cycle stage (e.g., First Review, Second Review, etc.);
- SOP number and full SOP title [SOP number will be modified, if necessary, to reflect its designated revision number in accordance with SOP ADM-101 Format for Standard Operating Procedures;
- Name of individual requesting the review and approval (i.e., name of Manager, Quality Assurance or authorized designee);
- The due date for submitting comments, suggestions, or questions to the Manager, Quality Assurance or authorized designee;
- Response codes for individual reviewers to indicate (1) = acceptable as written, (2) acceptable with indicated changes, or (3) unacceptable for the indicated reasons;
- A space for signatures and dates corresponding to each designated reviewer;
- Space for comments, suggestions or questions.

6.1.6 If warranted, the Manager, Quality Assurance, or authorized designee, may convene meetings of appropriate SAH personnel, consultants, and other authorized designee(s) to provide additional information and comments with regards to the SOPs under review.

6.1.7 As appropriate, the Manager, Quality Assurance, or authorized designee, will incorporate the comments and recommendations supplied by the designated reviewers into the revised SOP draft.

6.1.8 The above review and approval process may be repeated as necessary until all designated reviewers have indicated their acceptance of the SOPs under review.

6.1.9 SOPs that have undergone successful review and approval will be submitted to the Vice President, Clinical Development for final approval.

6.2 Expedited Reviews

6.2.1 Requests for revision of SOPs may be generated by SAH employees, contractors, vendors and other authorized designees who are impacted by clinical development procedures.

6.2.2 Requests for revisions will be submitted to the Manager, Quality Assurance, or authorized designee, by completing the Request for Revision Form [see Appendices] which includes the following information:

- SOP number and title
- Reason for requested revision
- Name of individual requesting the revision, and date of request
- Name of individual (i.e., name of Manager, Quality Assurance or authorized designee), and date of approval for the request
- Date of SOP revision

6.2.3 Based on the nature of the requested revision, the Manager, Quality Assurance, or authorized designee, will determine if a request for an SOP revision can best be addressed through an expedited review and approval process or during the planned annual review cycle.

6.3 Retention of Records

The Manager, Quality Assurance, or authorized designee, will retain completed SOP Routing Forms and SOP Request for Revision Forms until such time as the respective SOPs have been successfully reviewed and approved.