STANDARD OPERATING PROCEDURE

TITLE:	Project Management Standard Operating Procedures	SOP #:	OMN-110.00
DEPT:	Quality Assurance	REVISION #:	1.0
PREPARED BY:	James Lilliech	EFFECTIVE DATE:	09/1/2020
APPROVED BY:	Stephen M Casey, Partner		Page 1 of 4
SIGNATURE:	Stephen Casey	SIGNATURE DATE	

1.0 Purpose

1.1 To describe the process by which Project Management will be conducted with OMNI-HC for all projects.

2.0 Scope

2.1 These procedures apply to all of OMNI-HC's service providers including; any employees, consultants, and contractors participating in services or other efforts managed by OMNI-HC for a client.

3.0 Definitions

3.1 SOP - Standard Operating Policy and/or Procedure.

3.2 O365 - Office 365 Suite

3.3 Project - A properly authorized job for a client or a potential client.

3.4 SOW - Statement of Work

3.5 OPS - Operations Personnel

3.6 CDA – Confidentiality Disclosure Agreement

3.7 PD – Project Management Personnel

4.0 Responsibility

4.1 All OMNI-HC Program directors, project managers, subject area experts, operations, and management personnel will follow the procedures and guidelines presented in this document.

4.2 The OMNI-HC 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 management personnel receive adequate training to follow the instructions contained within this SOP.

5.0 Outline

5.1 The MP, or authorized designee, will ensure that each new Projects have the required naming conventions, SharePoint site(s), and QuickBooks presence/account.

5.2 The Program Director and Project Manager will follow the workflow listed in this document to ensure a smooth transition from onboarding into Project Development workflow.

6.0 Procedures

6.1 The procedures following will be the responsibility of the Program Director and Project Management personnel (PD) unless otherwise identified. These responsibilities cannot be delegated outside of the PD team.

6.2 Upon receipt of a fully executed SOW, management and operations personnel will onboard the project for the project execution team (e.g. create a sharepoint folder on the Omni-HC server and create project time account in Quickbooks) as outlined in SOP 104, 105, and 108.

6.3. Project Initiation

6.3.1. Intake and Scoping: Upon receiving a client inquiry, the PD will gather information using the agreed upon Scope of Work, a client briefing, and/or intake form. This will define project goals, target audience, deliverables, timelines, and budget.

6.3.2. The PD will utilize the individual Project Overviews or the original budget to identify scoped personnel hours.

6.3.3. Kick-off Meeting: The PD will conduct a kick-off meeting with the client and internal team (specialty experts, writers, editors, support, etc.) to clarify the project plan, timeline, and responsibilities and make any necessary changes in the execution of the plan.

6.3.3. Project Planning: The PD will develop a project plan outlining key milestones, deliverables, deadlines, resource allocation, and communication plan (who, what, when, how).

6.3.3.1 Stages of Project: Each project will have at least two rounds of revision, each round of revision will require adherence to the steps that follow.

6.4. Management of Content Creation and Revision

6.4.1. The PD will monitor the progress of content development and revision by writers. This may involve setting up regular check-ins, reviewing drafts at key stages, and providing feedback.

6.4.2. All content development will be done following SOP 106 using O365 or client designated content management system to ensure and maintain good content development practice.

6.4.3. If AI writing assistants are utilized, the PD should ensure writers understand how to leverage them effectively while maintaining scientific accuracy and adherence to the project brief.

6.5 Internal Review Management

6.5.1. The PD will assign internal reviewers and ensure they have access to necessary style guides, reference materials, and project briefs.

6.5.2. The PD can utilize AI pre-screening tools to generate guide documents for internal reviewers, allowing them to recognize high-risk sections or areas.

6.5.3. The PD will facilitate communication between writers and reviewers, addressing any discrepancies or questions that arise.

6.6. Client Review and Feedback

6.6.1. The PD will be responsible for the collation of all comments or revisions from the internal review and ensure all revisions are made and a copy of the latest version is stored on the O365 project sharepoint site.

6.6.2. The PD will prepare deliverables for client review, ensuring they are clear, concise, and formatted according to client specifications.

6.6.3. The PD will facilitate the transmission/submission of the content to the client for review either directly or through a submissions specialist.

6.6.4. The PD will maintain communication with the client during the review process, promptly address client queries, and schedule follow-up meetings if needed.

6.6.5. The PD will collate all client comments and revisions and present to writers and begin the revision process by initiating at steps 6.4 again.

6.6.6. The PD should be prepared to manage client expectations regarding turnaround times for revisions based on the complexity of the feedback.

6.7. Quality Management

6.7.1. Quality Checks: Throughout the content lifecycle, AI tools can be used to check for formatting inconsistencies, and missing information.

6.7.2. Version Control: A clear version control system will be maintained for each content related project to track changes made during the project. Version control will be the responsibility of the PD and the writers as outlined in SOP 106.

6.7.3. Scientific/Medical Review: If required, a thorough review of the scientific and medical content will be done by a scientific or medical expert. In this case a scientific or medical expert is defined as a terminally degreed person with experience in the therapeutic area.

6.8. Project Completion and Delivery

6.8.1. Final Review and Sign-off: A senior reviewer will conduct a final review of the deliverable to ensure overall quality, scientific accuracy, and adherence to client specifications.

6.8.2. Quality Audit Report: The PD will generate a final report summarizing all identified issues, reviewer feedback, corrective actions taken, and confirmation of regulatory compliance (if applicable).

6.8.3. Delivery and Archiving: The PD will deliver the final project materials to the client and archive them securely within the project O365 sharepoint site for future reference.

6.9. Project Closure

6.9.1. Project Debrief: The PM will conduct a debriefing session with the project team to discuss successes, challenges, and areas for improvement.

6.9.2. Client Satisfaction Survey: The PM will send the Omni-HC client satisfaction survey to gather feedback on the project experience.

7.0 Standards of Conduct

7.1 OMNI-HC Teams working on project management will follow the OMNI-HC guidelines below pertaining to their conduct and relationships. OMNI-HC employees and subcontractors will be aware of their responsibilities to the company and to fellow team members.

7.2 OMNI-HC will take a constructive approach to ensure that actions that would interfere operations or an employee's job are not continued.

7.3 Employees or subcontractors not conforming to OMNI-HC standards will result in one of the following forms of disciplinary action:

- verbal warning
- written warning
- termination

7.4 To arrive at the proper course of disciplinary action, OMNI-HC will consider the seriousness of the infraction, past record of the employee, and circumstances surrounding the matter will be considered.

7.5 Although it is impossible to identify every possible violation of standards of conduct, the following is a partial list of infractions that will result in disciplinary action:

- Falsifying company records including application for employment
- Revealing confidential information of any kind to anyone outside the company
- Theft, fraud, embezzlement, or industrial espionage
- Using company equipment, material, copy machines, office supplies, computers, computer files, electronic mail, mail systems, time or information for unauthorized purposes
- Abusing, destroying, or wasting company property or equipment
- Excessive absenteeism or tardiness
- Performance that does not meet the requirement of the position or that does not
- comply with company standards
- Working under the influence of drugs or excessive alcohol or bringing illegal drugs or drugs obtained without a valid prescription written for you by a licensed physician to any meeting or conference.
- Immoral or indecent conduct
- Engaging in any illegal activity while on the job or on company property
- Insubordination or the undermining of OMNI-HC, it's subsidiaries, or any of its employees or clients
- Use of language intended to provoke or threaten anyone while on the job or on company property, or use of obscene or profane language that is excessive or that can be heard by clients
- Interfering with an employee and the performance of his or her company duties
- Violation of any other policy of OMNI-HC as set forth in this Handbook
- Verbal, visual, or physical conduct constituting sexual harassment