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# Standard Operating Procedures for the collection of information Remotely via Phone Calls in healthcare organizations

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### Abstract

The purpose of this paper is to describe procedures for how members of a healthcare organizations should handle phone calls to ensure, enhance, and implement quality measures and to reduce errors in the collection of information [1].

This Standard Operating Procedure (SOP) applies to all phone calls regarding Patient Support and/or Patient Oriented Programs conducted by an organization and all employees who receive phone calls [2]. It is the responsibility of employee manager's and the Quality Assurance manager to ensure all employees adhere to the defined procedures [2].

Key words: SOPs; Collection; Information; Remote; Phone Calls; Healthcare organizations

## Introduction

#### **Employee Training**

- Organizations should create a defined procedure for handling phone calls using defined procedures for creating Standard Operating Procedures. This phone script should then be approved by the Marketing Authorization Holder before being communicated to agents [3].
- The organization is responsible for conducting and documenting phone training for each agent before they begin work to ensure they understand accepted procedures.
- Each agent will be trained to spot, record, report, and archive Adverse Events as per the organization's defined procedures [4].

- Each agent will be trained to secure patient's consent for phone call recording at the start of each call. If consent is not given, the call will be terminated [5].
- Simulated calls will be carried out before employees experience actual patient interactions to ensure good communication and adherence to phone procedures. These simulations will also test the employee's awareness and application of Adverse Event (AE) reporting procedures [6].
- The organization will confirm that each agent follows the approved script. A printed copy will be present in front of each agent's desk for easy availability [7].
- All out-bound and In-bound calls will be recorded, it is the responsibility of the agent and their direct manager to confirm that the recording is active before each call
- Complete and signed induction plan for Marketing Authorization Holder call center educators will be provided upon hiring

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- At the start of the project, each agent's first 5 patient interactions will be supervised by the direct manager for quality control purposes [8].
- Each agent will be required to fill out a phone call handling form after each call for quality control purposes [9].

#### Procedures

#### **Call Quality Assurance Procedures**

- It is the responsibility of the Agents' Manager or Quality Assurance manager to perform Test Calls on a daily basis before the start of taking calls to validate the recording/archiving system and to test sound clarity for call participants. This Test Call will be remain on the system records for proof of testing [10]
- It is the responsibility of the Agent's manager or Quality Assurance manager to perform random daily audits of 5% of calls per agent per project ensure compliance with appropriate procedures, including and not limited to post-vaccination adverse events, Health Professional Communication, Business Continuity Plan and fulfillment of requested Marketing Authorization Holder task orders, including and not limited to the approved script, transcript, patient consent, etc.

## Results

#### **Deviation Management**

• When deviations from phone handling protocol are identified by any means, (e.g. during random sample checks by the organizations managers, during source data verification processes

(SDV)) deviation reporting procedures will be followed to resolve the issue(refer to deviation Standard Operating Procedures) [11].

# Discussion

- Deviation reporting should occur within 24 hours of the incident, at which time the Marketing Authorization Holder will be notified and the agreed upon actions carried out to resolve the deviation.
- Upon review of the deviation, the related agent may be suspended for re-training at which time the agent will sign a consent for re-training. If the deviation does not warrant full re-training, the agent will not take any new calls until the deviation has been discussed and corrected by a senior officer.
- When the call agent resumes duties after retraining their first 5 calls will be accompanied and supervised by the direct manager.
- Monthly meetings will be held to share deviation incidents for continuous learning and improvement.

# Conclusion

• In case of Adverse Events reporting during a call, the agent will not start a new call before reporting the event through the Adverse Events reporting procedure (refer to Pharmacovigilance and Adverse Event Standard Operating Procedure).

Project Name:			
Agent's Name: Call No.			
Call Time:			
Date:			
Written Script followed	YES	NO	
Availability of Patient Consent	YES	NO	
Adverse event elicited	YES	NO	
In case of Adverse event, Adverse event Reported	YES	NO	
Comments			

Phone Call Handling Checklist Form [12]

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# Project Name: Agent Name: Call Date & Time: Auditor Signature: • If there is a Written Transcript, state your comments mentioning the integrity with the voice call. • Was the approved script followed? • Is there an Adverse event elicited & was it reported? Is there an Adverse event elicited & was it reported? • Was the patient consent secured?

**Daily Random Sample Audit Form [13]** 

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