# EXAMPLE Standard Operating Procedure:

# Obtaining and Integrating Site & Investigator Feedback During Protocol Finalization

## I. Purpose

To outline a standardized process for collecting, evaluating, and incorporating site and investigator feedback into the near-final clinical study protocol to enhance operational feasibility, improve compliance, and support successful site activation and trial execution.

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## II. Scope

This SOP applies to sponsor teams responsible for protocol development, clinical operations, monitoring, and site management.

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## III. Definitions

**Site Feedback:** Input from site investigators and/or site study staff regarding operational practicality, regulatory feasibility, resource requirements, and risks to compliance.
**Near-Final Protocol:** Protocol version prepared for final feasibility review prior to governance or IRB/ERC submission.

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# IV. Roles & Responsibilities

### Clinical Operations Lead / Project Team Lead

- Identify site-facing elements needing feasibility review
- Coordinate site selection for feedback
- Review feedback for operational implications

**CRA / Site Manager**

- Facilitate communication with site staff
- Provide context on site capabilities and common operational challenges
- Support the documentation of feedback

**Protocol Author / Medical Lead**

- Assess scientific and safety implications of suggested changes
- Determine impact on endpoints and assessments

**Regulatory Lead**

- Evaluate compliance, GCP, and documentation implications

**Sponsor Study Leadership**

- Approve final protocol decisions
- Confirm justifications for changes not implemented

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# V. Workflow

## 1. Identify Components Requiring Site Feedback

Identify aspects of the protocol most likely to impact site operations, including:

- Visit schedule and timing
- Data entry requirements
- Source documentation expectations
- Investigational product handling/logistics
- Safety reporting procedures
- Regulatory packet and essential document requirements
- Monitoring plan feasibility

Prepare a site-friendly summary or checklist to streamline review.

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## 2. Select Sites & Communicate Expectations

Choose 3–10 experienced investigators or representative sites based on:

- Prior performance
- Geographic/operational diversity
- Study-specific expertise

Communicate:

- Objectives of the review
- Anticipated timeline
- Confidentiality expectations
- Materials provided (protocol synopsis, visit schedule, sample CRFs, monitoring plan excerpt)

This approach parallels site evaluation and readiness processes.

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## 3. Use Structured Feedback Tools

Create tools such as:

- Feasibility questionnaires
- Operational risk checklists
- Investigator roundtable guides
- CRF/procedure burden assessments

Include targeted questions on:

- Resource intensity
- Training requirements
- Likelihood of protocol deviations
- Safety oversight burden

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## 4. Collect Feedback

Gather feedback through:

### Interviews with Investigators

- Conduct via web meeting or phone

- Explore real-world workflow barriers
- Capture regulatory/IRB considerations

### Site Staff Focus Sessions

- Involve coordinators, pharmacists, data managers
- Identify practical site-level challenges

### Written Feedback Forms

- Offer structured templates
- Allow sites to involve multiple staff members

Document:

- Operational concerns
- Safety or compliance risks
- Suggestions for alternative approaches

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## 5. Analyze & Categorize Feedback

Group findings into:

- **High Impact:** Feasibility issues likely to cause deviations, delays, or regulatory risk
- **Moderate Impact:** Process improvements or potential efficiency gains
- **Low Impact:** Optional enhancements or site preferences

Assess implications for:

- Clinical Monitoring Plan
- Essential document requirements
- Training plans
- Site initiation preparation

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## 6. Determine Final Protocol Changes

For each suggestion, classify as:

- **Accepted and incorporated**

- **Partially incorporated**
- **Not incorporated with justification**

Review decisions with:

- Protocol authors
- Clinical operations leadership
- Regulatory team

This aligns with governance practices.

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## 7. Communicate Outcomes Back to Sites

Provide a clear summary:

### “You Said / We Did (and Why)”

- Changes made based on investigator/site feedback
- Rationale for items not changed
- Operational clarifications added to support sites

Delivery options:

- Email summary
- Webinar-style debrief
- Updated protocol package with annotated changes

This “closed loop” communication supports ongoing site engagement and readiness.

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## 8. Archive Documentation

Store:

- Feedback tools used
- Raw site comments
- Decision logs
- Summaries and communications sent to sites
- Updated version of the protocol and related operational materials

This supports audit readiness.