

## **EXAMPLE Standard Operating Procedure:**

# **Obtaining and Integrating Patient & Caregiver Input During Protocol Finalization**

## **I. Purpose**

Establish a consistent, patient-centered process for gathering, evaluating, and incorporating patient and caregiver feedback into near-final clinical study protocols.

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## **II. Scope**

This workflow applies to all teams involved in protocol design, clinical operations, and patient engagement.

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## **III. Roles & Responsibilities**

### **Clinical Team / Protocol Authors**

- Identify protocol sections requiring feedback
- Develop plain-language summaries and visual aids
- Review and implement recommended changes

### **Patient Engagement Lead**

- Recruit representative patients/caregivers
- Provide discussion guides
- Facilitate interviews or focus groups

### **Logistics / Coordinator**

- Schedule sessions
- Distribute materials
- Document and archive feedback

## **Study Leadership**

- Review recommendations
  - Approve protocol updates
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## **IV. Workflow**

### **1. Identify Feedback Needs**

Determine which elements of the protocol require patient or caregiver review:

- Visit schedule and burden
- Procedures and assessments
- Travel and technology requirements
- Comprehension of key risks and commitments

Provide supporting materials in plain-language or visual formats (e.g., simplified protocol summary or visit schedule graphic).

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### **2. Recruit Participants**

Select 3–10 participants who reflect the intended study population.

Provide:

- Purpose and expectations
  - Time commitment
  - Confidentiality requirements
  - Plain-language review materials
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### **3. Prepare Feedback Tools**

Develop consistent, structured tools such as:

- Interview guides
- Rating scales
- Written questionnaires

- Discussion prompts

Ensure all documents use clear, accessible language.

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## **4. Collect Feedback**

Use one or more methods:

### **Individual Interviews**

- Conduct via phone, video, or in person
- Follow a semi-structured guide
- Explore anticipated barriers

### **Focus Groups**

- Capture shared experiences and consensus themes
- Encourage open discussion

### **Written Surveys**

- Provide flexibility for asynchronous feedback
- Allow participants to review at their own pace

All sessions should be respectfully facilitated and carefully documented.

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## **5. Analyze & Synthesize Input**

Organize feedback into categories:

- High-impact issues affecting feasibility or burden
- Moderate improvements
- Low-impact or informational points

Identify themes, risks, and recommended operational changes.

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## **6. Determine Protocol Changes**

For each recommendation, document the decision:

- **Accepted** (fully implemented)
- **Modified** (partially implemented)
- **Not Accepted** (with rationale)

Route decisions through protocol authors, operations, and governance as needed.

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## 7. Communicate Back to Participants

Share a clear, plain-language summary highlighting:

- What was heard
- What was changed
- What could not be changed and why

This reinforces respect and transparency.

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## 8. Archive Documentation

Store:

- All materials shared with participants
- Notes, transcripts, or surveys
- Summary reports
- Decision logs
- Updated protocol sections

Ensure traceability for quality audits.