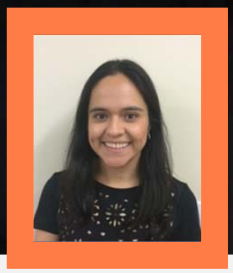
CTN WEB SEMINAR SERIES: A FORUM TO EXCHANGE RESEARCH KNOWLEDGE

National Drug Abuse Treatment Clinical Trials Network

Developing an Effective Standard Operating Procedure (SOP) for Research Staff Engagement with Participants Lost to Incarceration



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Discussion Objectives

- Discuss the importance of a SOP
  - o Distinguish between MOP *vs* SOP
  - o Consider benefits of implementing a SOP--prisoner engagement at research sites
- Outline the components of an effective SOP for prisoner engagement
- Discuss the general process of SOP development and tips

MOP *vs* SOP

Manual of Operating Procedures (MOP)

- A handbook that details or outlines procedures for study conduct and operations across multiple sites

Standard Operation Procedures (SOP)

- Detailed, **written** instructions specific to a site for the performance of a specific function to achieve uniformity

Within the context of clinical research, a SOP is an effective tool to:

- centralize guidelines and standards for a procedure
- minimize risks
- maintain consistency in performing the procedure

Why are SOPs needed?

- Increase compliance with study protocol
  - o Minimize protocol departures/deviations
- Re-enforce knowledge of procedure performance, even after training
- Ensures effective coverage by research staff over the course of a study
- Encourages quality control; subject to routine evaluation

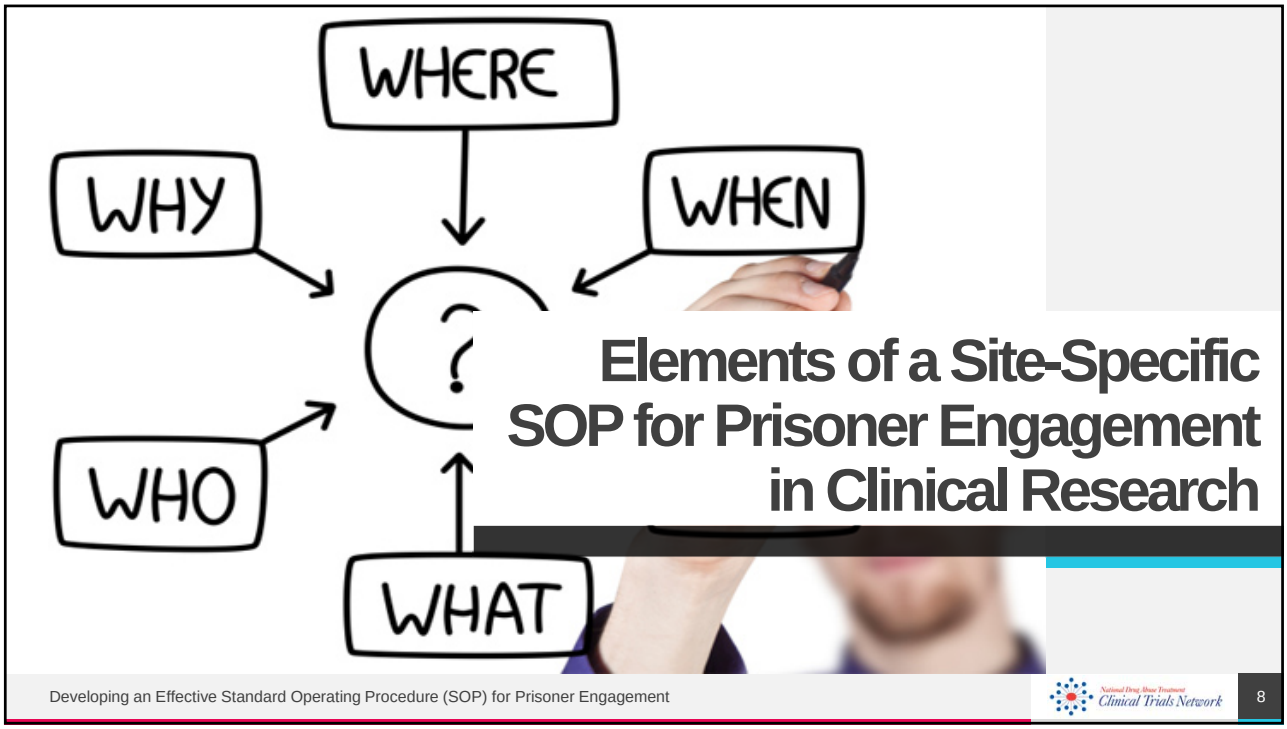
Benefits

Why are SOPs needed?

Study Operations that May Require SOPs

Examples

- **Retention Procedures (participant tracking, prisoner assessment, prisoner engagement, follow-up, compensation)**
- Participant Safety (emergent psychiatric and medical events)
- Other Study Operations (collecting informed consent, biological assessments, MHR abstraction)



Elements of a Site-Specific SOP for Prisoner Engagement in Clinical Research

Elements of a Site-Specific SOP for Prisoner Engagement

I. Purpose/Rationale

This SOP is a site-specific supplement outlining guidelines on procedures for locating and completing follow-up visits with incarcerated participants.

II. Locating Incarcerated Participants

- Locator Form
- Search strategies (e.g., first, last name, alternative spellings)
- Public or private databases
- Local resources (e.g., county or city level)
- State resources
- Federal resources

Elements of a Site-Specific SOP for Prisoner Engagement

III. Contacting Facilities and Maintaining Confidentiality
- o Facility contact information
- o Outline a roadmap for who to contact
- o Describe how to interact and what to say

IV. Contacting the Participant
- o Research site-required approvals (e.g., site PI or Lead Node)
- o Establishing contact with a participant lost to incarceration
- o Scheduling a Visit
- o Setting up a Visit by Phone

Elements of a Site-Specific SOP for Prisoner Engagement

V. Preparing for the Study Visit
- o Navigating to facilities (e.g., map the route/transportation specifics)
- o Guidelines for proper, acceptable identification

VI. Research Staff Etiquette
- o Facility-specific requirements or rules
- o Procedures before and upon arrival
- o Procedures for facility departure

VII. Conducting the Study Visit
- o Study Materials
- o What to take: blank CRFs, etc.
- o What not to take: PHI, etc.

Elements of a Site-Specific SOP for Prisoner Engagement

VIII. Participant Compensation
- o Acceptable methods of transfer
- o Assessing/documenting participant preference(s)

IX. Safety
- o Psychiatric vs. Medical events
- o Procedures to follow within the facility
- o Research Staff Precautionary Measures

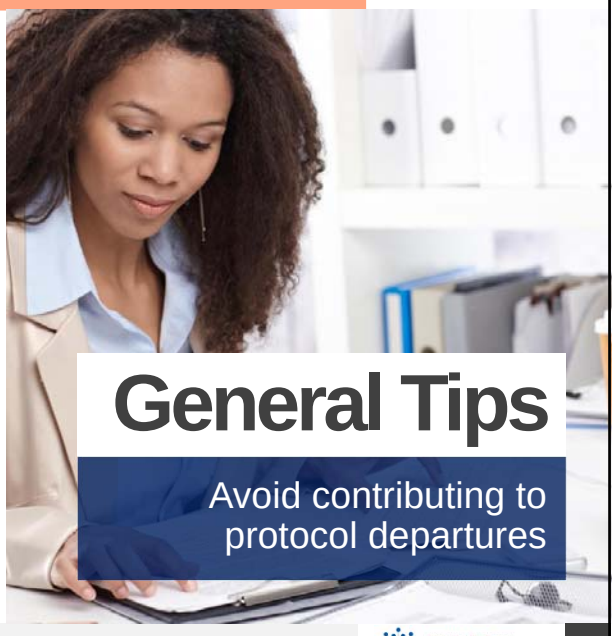
SOP Development

General Process

- Typically collaborative team approach
- Established during study pre-implementation as part of site readiness activities
- Reviewed for completeness

- Consult with researchers familiar with the process
- Use consistent study terms and language
  - o "Participant" not "Subject" (NIDA CTN Trials)
  - o Refer to the identified study roles – Research Assistant, Study Coordinator, PI
- Define acronyms
- Reference protocol and MOP when appropriate to reduce unnecessary duplication

- Verify content is free from contradictions to existing study procedures
- Set aside time to review SOPs and train all necessary site research staff prior to implementation
- Revise SOPs as new or expanded information is available and when process changes occur



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Thanks for your participation.