METRC Policy & Procedure Manual

Title: Guidance for Developing Study-Specific SOPs

Document ID: PPM_Study Specific SOP Guidance Document_V1.0

Document History:

Version	Version Date	Approved by	Version Approval/ Effective Date	Summary of Changes
1.0	4/2/2025	Lauren Allen	4/2/2025	N/A

Document Review Schedule: Annual

Purpose: Study-Specific SOPs complement METRC's general SOPs by detailing procedures tailored to the specific needs of an individual study. These SOPs address additional requirements such as regulatory considerations, sponsor-specific needs, and protocol-specific details.

Scope: This SOP applies to all personnel responsible for creating, updating, and executing study-specific SOPs.

Responsible Parties: METRC Coordinating Center leadership are responsible for creating, reviewing, and updating this guidance. Project Directors, or alternate individuals designated by the study PI, are responsible for drafting the Study Specific SOP. The given study's Clinical PI and the MCC PI are responsible for reviewing and approving the final version of the Study Specific SOP.

Informed Stakeholders: METRC clinical site investigators and research staff.

Steps to Develop Study-Specific SOPs

1. **Review General SOPs**
   Familiarize yourself with METRC's general SOPs (e.g., Certification, Monitoring, Study Close-Out) to ensure the study-specific SOP builds upon standardized practices.
2. **Identify Study-Specific Details**
   Determine additional requirements based on:
   - FDA regulation status (e.g., source document verification or investigational product management for FDA-regulated studies).
   - Sponsor-specific guidelines and expectations.
   - Study-specific factors such as risk level, design complexity, or unique data management needs.

3. **Customize Procedures**
   Add study-specific details to each relevant section (e.g., monitoring frequency, safety reporting requirements). Use the template structure to ensure consistency with METRC formatting.

4. **Engage Key Stakeholders**
   Collaborate with the MCC, sponsors, and other stakeholders to validate study-specific customizations and confirm alignment with study objectives and regulatory requirements.

5. **Document and Approve**
   Finalize the study-specific SOP and obtain approval from the Study Principal Investigator (PI) or designated authority before study initiation.

TEMPLATE FOR STUDY-SPECIFIC SOPS

Document Header

- **Title:** [Study Name] Study-Specific SOP
- **Document ID:** [Study Name_Specific_SOP_V#.0]
- **Document History Table** [Version, Version Date, Approved By, Version Approval/Effective Date, Summary of Changes]
- **Document Review Schedule**

Purpose: *Example: This SOP outlines study-specific procedures for [Study Name], supplementing METRC's general SOPs to address protocol-specific, sponsor-specific, and regulatory requirements.*

Scope: *Example: This SOP applies to all participating sites and study team members involved in [Study Name]. It outlines additional requirements and procedures not covered in METRC's general SOPs.*

Responsible Parties: Define roles (e.g., MCC Monitors, Site PIs, Study Coordinators) and their study-level responsibilities.

Informed Stakeholders: Identify personnel requiring notification or access to the SOP for awareness without direct responsibility.

Study-Specific Procedures

1. Certification Requirements

- Address study-specific certification details:
    - Training requirements for FDA-regulated studies.
    - Site-specific training needs and documentation methods.

2. Monitoring

- Tailor monitoring procedures:
    - Specify monitoring frequency, intensity, and methods based on study design.

- Include requirements for FDA-regulated studies (e.g., source document verification).

3. Conflict of Interest Reporting

- Outline processes for identifying, documenting, and addressing conflicts of interest.

4. Data Management

- Provide study-specific data entry guidelines for REDCap.
- Include query resolution timelines and final database lock procedures.
- List of standardized reports to be generated for study management purposes using the Analytic Data System.

5. Investigational Product Management

- Detail shipment, storage, and documentation requirements.
- Address additional sponsor or regulatory needs for investigational drugs or devices.

6. Safety Reporting

- Specify thresholds and timelines for reporting Serious Adverse Events (SAEs) and Unanticipated Problems (UPs).
- Include DSMB coordination and safety oversight details.

7. Adjudication

- Use of Adjudication Committees; composition of committees; scope of work

8. Study Close-Out

- Describe study-specific close-out requirements:
  - Final IRB closure timelines.
  - Archiving requirements for study documents.

Templates and Resources

- Certification forms tailored for the study.
- Monitoring visit checklists.
- Site-specific delegation logs.
- IRB submission templates.

Terms and Abbreviations

Legacy and Reference Documents

- Reference relevant METRC general SOPs (e.g., Certification, Monitoring, Site Close-Out).

- Include regulatory references (e.g., FDA guidelines, GCP standards).