METRC Policy & Procedure Manual

Title: Clinical Site and Staff Certification SOP
Document ID: PPM_Clinical_Site_Certification_SOP_V1.0

Document History:

Version	Version Date	Approved by	Version Approval/ Effective Date	Summary of Changes
1.0	11/01/2024	Lauren Allen, Operations Director	11/01/2024	Initial version consolidating certification requirements, approval, and record-keeping processes

Document Review Schedule: Annual

Purpose

This SOP outlines the standardized certification process for METRC clinical sites and study staff, ensuring that sites and personnel are prepared and qualified to conduct METRC study activities. Certification documentation verifies that study-specific training has been completed, required regulatory approvals and credentials are in place, and site-specific processes are aligned with METRC standards.

Scope

This SOP applies to all METRC clinical sites and study staff seeking certification to conduct METRC-related study activities. It specifies minimum certification documentation, additional study-specific requirements, and procedures for certification approval and maintenance.

Audience

This SOP is intended for METRC Coordinating Center personnel, clinical site teams, and study staff involved in site and personnel certification processes.

I. Certification Requirements

Minimum Certification Documentation

- Clinical sites must complete and submit all necessary certification documents listed in the Certification Documentation Checklist to the METRC Coordinating Center. At a minimum, the following documents are required:
    - IRB Application Materials
    - IRB Approval Letter(s)

- DoD HRPO Approval (for DoD-sponsored studies)
- Form 1572 (for FDA-regulated studies)
- Clinical Site Certification Form (detailed below)
- Medical Licenses (clinicians only)
- Curriculum Vitae (CV) or Resume for each team member
- Human Subjects Research Training Certificate (required for all staff certification requests)
- Good Clinical Practice (GCP) Training Certificate (required for study PIs and research coordinators/assistants)
- Conflict of Interest (COI) Disclosures, updated annually

- Study-Specific Documentation: Additional documents may be required for certification, including IATA and CLIA certifications for studies involving sample handling or laboratory work.

Clinical Site Certification Form

- Purpose and Content:
  The Clinical Site Certification Form, once tailored for a specific study and completed by a site seeking certification approval, serves as an official summary record of critical information about the participating site. This includes essential administrative and approval details, expectations for screening and enrollment, and a complete listing of study team members.
- Key Components:
  The Clinical Site Certification Form provides a primary record verifying a site's readiness to begin study activities, documenting team members requesting certification, their roles, and associated training. Training documentation requirements will be specified in the study-specific certification plan and will cover:
  - Review of study materials (minimum)
  - Attendance or viewing of official study training sessions
  - Completion of any study-specific training with MCC staff
  - Any additional training as required by the study

Study-Specific Certification Plan

- For studies with certification needs beyond the standard requirements, the MCC will develop a Study-Specific Certification Plan outlining additional certification requirements. This plan may include:
  - Site-Specific Implementation Plans or SOPs: Sites may need to document study-specific procedures tailored to the study requirements.
  - Certification Calls or Site Visits: Certain studies may require initial or recurring certification calls or site visits to verify readiness.

    - Additional Documentation: Any study-specific documents or processes required for certification will be included in the plan.

- The Study-Specific Certification Plan will specify training requirements for the study, which will be reflected in all relevant certification resources, including the Clinical Site Certification Form, Approval Memo, Certification Table, etc. Study teams are responsible for updating template resources accordingly.

II. Certification Approval Process

Initial Certification Approval

- Upon receipt of all required documentation, including the Clinical Site Certification Form, the MCC Study Team will review materials to confirm site readiness. Certification is considered complete when all documents meet study requirements, verifying that the site and its personnel are qualified to carry out study activities.
- A Certification Approval Email will be sent to the site PI and study team, confirming certification status and authorizing access to study tools such as REDCap.
- Note on New Staff: Any new personnel joining a study must be fully certified by the MCC before beginning any study activities. Certification includes verification of training, submission of required documents, and formal approval by the MCC.

Certification Maintenance and Updates

- Certification is ongoing; new or replacement staff must be certified before they begin study activities. Sites are responsible for updating the MCC on team composition and providing certification updates as needed.
- Each staff member certified for a study must have an associated begin and end date, documented in the Certification Table, which tracks active certification periods and completion of study training.

III. Certification Record-Keeping

Certification Table

- The Certification Table is maintained by the MCC and logs all certified personnel at each site, including approval begin and end dates and roles. This table can serve as the Delegation of Authority Log when compliant with institutional policies.
- The Certification Table is updated as needed with any changes in team composition or certification status, ensuring comprehensive tracking of active and inactive study personnel.

Record Maintenance

- Certification documentation, including the Certification Table and Clinical Site Certification Forms, will be stored in a secure repository accessible only to authorized personnel.
- Sites should maintain certification records and certification-related communication (e.g., Certification Approval Emails) within their Regulatory Binders.

IV. Templates and Resources

The following templates and resources are included with this SOP to facilitate compliance with certification requirements:

- Certification Documentation Checklist: A checklist for required certification documentation, provided as a resource for sites to ensure all necessary documents are submitted.
- Certification Approval Email Template: A standardized email template for notifying sites of certification approval.
- Clinical Site Certification Form: A form capturing essential certification details, including team roles, submitted documents, training completed, and begin/end dates for each certified staff member.
- Certification Table Template: A table template to log certified personnel, their roles, begin and end dates, and associated training.

V. Legacy Documents Summary

This SOP consolidates and replaces the following legacy documents, streamlining and unifying certification processes and strengthening training documentation.

- Standards and Procedures for Clinical Site Certification (Effective Date: 9/6/2019): Provided description of standards and procedures for clinical site certification.
- Clinical Site Certification Documentation Checklist Template (Effective Date: 9/6/2019): Provided the initial list of required documentation for clinical site certification. A refreshed template has been provided as a resource; its use is strongly recommended but not required.
- Clinical Site Certification Approval Email Template (Effective Date: 9/6/2019): Established the format for communicating certification approval. A refreshed template has been provided as a resource; its use is strongly recommended but not required.
- Clinical Site Certification Form Template (Effective Date: 5/19/2022): Provided a template for study teams to use in developing the Clinical Site Certification Form for a given METRC Study. A refreshed template has been provided as a resource; its use is strongly recommended but not required.

VI. Document Dissemination and Training

- This SOP will be distributed via SharePoint, with notification to all relevant personnel by email.
- Training: Coordinating Center personnel involved in certification must confirm they have reviewed and understood this SOP by completing the self-certification form.

VII. Terms & Abbreviations

- MCC: METRC Coordinating Center
- GCP: Good Clinical Practice
- COI: Conflict of Interest
- REDCap: Research Electronic Data Capture