Title: Standards & Procedures for Provisional Site Certification

Document ID: SM_Imp_SiteCert_Prov

Version & Publication Date: V 1.0, 11/22/2019

Previous Version Date: N/A

General Description & Purpose: This document describes the METRC Coordinating Center's standards and procedures for issuing provisional certification to a site.

Corresponding Documents:

  A. Provisional Certification Approval Email Template
  B. Provisional Certification Assessment Email Template
  C. Transition from Provisional to Full Certification Approval Email Template

---

I. Provisional Site Certification Definition and Purpose

METRC Policy Regarding Provisional Site Certification

Provisional Site Certification is an <u>optional step</u> in an overall Site Certification Process which an MCC Study Team may wish to implement as an additional quality assurance activity. Study teams which elect to implement Provisional Site Certification are required to follow the standards and procedures outlined in this document and to use the corresponding document templates.

Purpose of Provisional Site Certification

Provisional Site Certification is an additional quality assurance step positioned prior to issuance of full Clinical Site Certification. Provisional Site Certification allows the site participating in the given study and the MCC study team to evaluate the site's ability to screen and enroll participants, to implement study procedures, and to collect and enter complete and timely study data. During the Provisional Certification period, the site is approved to enroll and collect data on a pre-specified number of study participants, e.g., an initial 3 participants. The MCC Study Team works closely with the site during this time and prospectively monitors the site's fidelity to the study protocol and quality of the data entered into the study database.

II. Provisional Certification Procedures

Site Requirements Prior to Provisional Certification Approval

Sites must fulfill all the documentation submission requirements prior to Provisional Certification Approval, just as they do prior to standard Certification Approval. These requirements are described in detail in the PPM document: Standards & Procedures for Clinical Site Certification (V.f.ii SM_Imp_SiteCert).

Defining the Activities Permitted and/or required During Provisional Certification

The MCC study team determines, prior to study initiation, whether provisional certification will be employed as an additional quality assurance activity for the given study. The MCC Study Team also defines which study activities will be permitted and/or required of sites during the Provisional Certification Period. The complexity of the study protocol, the volume of baseline data collected, and the Study Team's expectations regarding how difficult it will be to collect the data, are all taken into consideration when making this determination. Participating sites are informed of the Provisional Certification parameters prior to study initiation.

Provisional Site Certification Procedures

Once a site has met all activity and documentation requirements, the MCC Study Team initiates the Provisional Certification Approval process. This occurs within 5 business days of the site and MCC Study Team verifying that all requirements have been met.

The procedures for issuing Provisional Certification Approval are the same as the procedures for issuing standard Certification Approval; the Provisional Certification Approval Email Template is used instead of the standard Certification Approval Email Template.

III. Monitoring Provisionally Certified Sites

Provisional Certification is intended to facilitate real-time, applied feedback between a participating site and the MCC Study Team. This means that the MCC Study Team is required to closely monitor provisionally certified sites' activity as soon as provisional certification approval is issued.

Review of Enrolled Participants and Assessment

The Study Team decides between reviewing the initial enrollments on a case-by-case basis or waiting and reviewing the initial enrollments all together. The Study Team closely monitors the enrollment notifications (auto-notifications via REDCap) and when the initial enrollment target is met, sends an email to the site reminding them to discontinue enrollment until further notice. The Study Team also notifies the MCC REDCap Administrator who then suspends the site's ability to enter any further Screening & Enrollment forms (CRF00). The notice to the site and REDCap Administrator may occur within the same email.

The MCC Study Team's thorough review of the data includes checks for completeness and timeliness. The review may also check for accuracy by requesting that the site provide copies of source documents which substantiate the study data. The review of the data may also be supplemented with qualitative information gathered via email exchanges or calls with the site. For example, a site may explain via phone call the reason that a particular data element(s) was entered late or why a data element was missing. These communications allow both the site and the Study Team to better understand how to implement the study protocol, particularly complex procedures or difficult-to-obtain data.

Communication of Findings & Recommendations to Provisionally Certified Sites

The MCC Study Team thoroughly documents any data quality problems or other issues of concern on a monitoring report of its choosing, e.g., an Excel spreadsheet, a Word document, etc. This report is then

sent to the site using the Provisional Certification Assessment Email template. The information on the monitoring report may be included as an attachment to the email or embedded within it.

IV. Transition from Provisional Certification to Full Certification Approval

In most cases, a provisionally certified site is transitioned to full certification approval after it addresses any specific data quality issues and overall areas for concern or improvement. There may be instances where the site is unable to overcome implementation challenges or data quality issues through factors beyond its control, e.g., if it is made clear during provisional certification that the site is unable to obtain the required data from an outside provider such as a local EMS provider.

The MCC Study Team will use the Transition from Provisional to Full Certification Approval Email template to formally grant full Certification Approval to the site. Upon full Certification Approval, the MCC REDCap Administrator will unlock all forms in the REDCap database and the site may reinitiate screening and enrollment activities.

_____

DOCUMENT HISTORY

- **V1, 11/22/2019**
    o Updates: N/A
    o Dissemination Method: Memo to MCC, Publication to Dropbox
    o Primary Author(s): Craig Remenapp & Lauren Allen
    o Stakeholders Engaged: MCC Study Managers
    o Formal Review or Approval Process: N/A
    o Name & Role of Trainer: N/A
    o Date & Venue of Training: N/A
    o Who Attended Training: N/A