

METRC Policy & Procedure Manual

Title: Dissemination & Training Plan for METRC PPM

Document ID: PPM_DPT

Version & Publication Date: V 3.0, 3/9/2020

Previous Version Date: V1.0, 6/12/2019, V2.0 6/28/2019

General Description & Purpose: This document describes the plan for disseminating and training personnel on the documents that together comprise METRC's Policy & Procedure Manual.

I. Navigating METRC's Policy & Procedure Manual

METRC's Policy & Procedure Manual is a compendium of documents where the component documents are published as they become newly available or when they are revised. There are two items within the compendium which exist to assist METRC-affiliated personnel in navigating the complete compendium: the Table of Contents and the Index. These items are described briefly below.

The Table of Contents takes the format of an outline. Contents are organized into major content categories and further into multiple sub-category levels. The Table of Contents is the best source for determining how individual pieces of the Policy & Procedure Manual fit into the larger METRC picture. The pieces of the Table of Contents which correspond to published (or to-be-published) documents are also identified in the Index; pieces of the Table of Contents which are only for organization purposes are not mapped to the Index (i.e., subcategory titles).

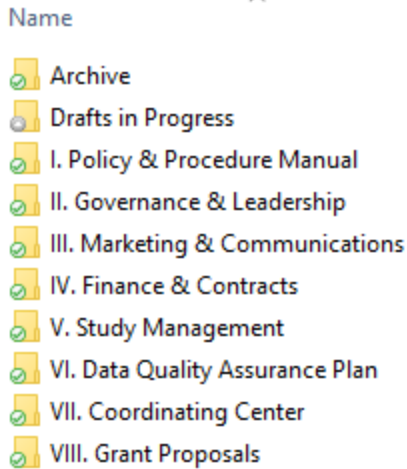
The Index identifies additional important information about each Policy & Procedure Manual document. This information includes: the Document ID (i.e., the short name), the document type (e.g., procedures, template, etc.), all version dates, and training requirements for internal and external personnel.

II. Standards and Procedures for Maintaining the Policy & Procedure Manual Document Repository

Main Repository Location & Folder Structure

The master repository for the METRC Policy & Procedure Manual is in the METRC Dropbox folder called "METRC Policy & Procedure Manual"- see Figure 1.

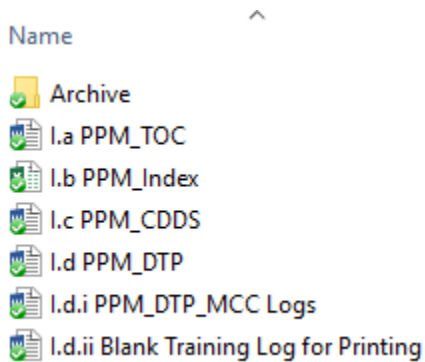
Figure 1. METRC Policy & Procedure Manual Dropbox Folder Organization



The main folder also contains an Archive folder and a Drafts in Progress folder. The main Archive folder is for materials archived from METRC’s archived Manual of Operations. The Drafts in Progress folder is intended to store drafts of PPM documents which are actively in progress.

The major components of the PPM each have their own subfolders which are organized consistent with the Table of Contents and Index using the document short name preceded by the list order. Each major component subfolder also contains its own Archive folder. These Archive folders are to be used for version dates of documents which were formally published to the METRC Policy & Procedure Manual. See Figure 2 for an example.

Figure 2. Example of Subfolder Organization



The repository is accessible by personnel of the METRC Coordinating Center and others affiliated with METRC by invitation only.

Publishing Documents to the Repository

Once a version date of a document is finalized, it is “published” as a PDF to the appropriate Dropbox folder. Microsoft Word versions of the documents are also maintained in the same place using the same naming conventions but should not be considered the published file; “Published”= PDF. The Word versions are preserved in order to have an editable file should revisions or updates to the document become necessary.

There are two exceptions to the *published=PDF* standard: 1) Table of Contents and 2) the PPM Index. These two files are intended to be used for PPM navigation and will be updated frequently. As such they will be maintained as “living documents” where instead of a version date, these two files will have a “last updated” date.

Website Repository

The “About Us” section of the METRC website is the secondary repository for the Policy & Procedure Manual. The Website repository is where most Consortium members at METRC sites, i.e., not at the METRC Coordinating Center, will access the PPM contents.

The PPM Index is posted as a separate file at the top of the page. Consortium members are instructed to use the Index for navigation purposes as described in the first section of this document. The remaining contents of the PPM are posted to the website using nested accordion folders organized consistent with the Table of Contents and Index.

Only PDF versions of PPM documents are posted to the METRC Website repository; no Word (i.e., editable) versions are posted. Similarly to the Dropbox repository, the Index is posted as an Excel file to maintain sorting functionality. Archived version dates will be taken down from the Website repository; archived documents may only be found in the Dropbox repository.

III. Policy & Procedure Manual Content Dissemination

The minimum standard for dissemination of PPM contents is publication to the main repository on Dropbox. Additional dissemination activities may be appropriate and may be undertaken at the discretion of the Executive Management Team.

When PPM contents are disseminated via email memo, the following template is used:

Subject Line

“METRC PPM Memo: <<PPM Document Title>>”

Email Body

“Please find attached a new METRC Policy & Procedure Manual document, “<<PPM Document Title>>”, <<Version Date>>. This document is published to the main, Dropbox Repository as of today. You are copied on this memo because your role within METRC dictates that you are required to be trained on this PPM document. Please read this document as soon as possible, seek clarification if needed, and then certify your training on your Training Log (Training Binder is housed in Room 357).

Here is the link to the PPM document in the Dropbox Repository: <<Dropbox Link>>

The PPM Table of Contents and PPM Index have been updated to reflect that the addition of this published document to the PPM. The “Last Updated” date on these two navigation tools is now <<Last Updated Date>>. Here is the link to the PPM TOC and Index in the Dropbox Repository: <<Dropbox Link>>.

A copy of this memo (sans attachment) is also filed in the central Training Binder.

Note: Make sure to include attachment before sending.

When disseminating an updated version of an existing PPM document, the same basic components of the above template are used. Where the above template references a “new” PPM document, the memo should instead reference an “updated” document. A brief description of the updates should also be included.

When PPM documents are disseminated in the form of a group training, a copy of the training materials, e.g., Power Point slides, will be filed in the central Training Binder.

IV. Policy & Procedure Manual Training

Specifying Training Requirements

Each document within the PPM has an intended audience and this audience must read or receive training on the document. The primary author(s) of the PPM document makes a recommendation on the appropriate audience to the Executive Management Team prior to the document publication. The Executive Management Team will amend and or approve this recommendation. Once approved, the audience for the PPM document will be indicated in the PPM Index.

There are 2 main audience categories: METRC Sites and METRC Coordinating Center. The METRC Sites category is further divided into Investigators and Research Staff. The Investigators category includes all Principal Investigators, Associate Investigators, and other Clinicians or Academic Investigators. The Research Staff subcategory includes all research staff of all levels.

The METRC Coordinating Center category is further divided into Investigators, Study Teams, Analysis Core, Informatics, Administration, and Finance. The Investigators category includes all MCC Principal Investigators and Associate Investigators. Study Teams includes Protocol Leads and Site Leads, Research Assistants, and others contributing to specific METRC studies, e.g., Interviewers. The Analysis Core consists of Senior Biostatisticians, Economists, Data Analysts and all others who contribute to regular reporting for METRC studies. The Informatics category includes all members of the Informatics Core, of which some members are located outside of the METRC Coordinating Centers, e.g., in the JHSPH Biostatistics Consulting Center. The Administration category consists of Administrative Coordinators, Editorial Assistants, and Research Assistants with administration-related duties. The Finance category captures all members of the METRC Finance Core as well as Investigators and Study Team members, e.g. Project Directors, who have input into or oversight of Study Budgets. In some instances, Finance-related PPM documents are shared outside of the METRC Coordinating Center with others within Hopkins Research Administration; these individuals are not required to document training.

Training Methods

There are multiple acceptable ways to receive training on PPM contents. The most straight-forward method is to independently read the contents. Group-training may also occur in venues such as Staff Meetings, web conferences, audio-only conference calls, etc. Ultimately it is up to the individual to certify that s/he read the document and/or received training; for Coordinating Center personnel, training verification procedures are also in place (described below).

METRC Coordinating Center Training Logs

Each member of the METRC Coordinating Center will have a Training Log which documents the contents on which the individual received training. MCC personnel are responsible for ensuring that their training logs are up-to-date and that their trainings have been verified.

Specific instructions for how to complete the Training Logs are specified on the logs themselves (see template document I.d.i PPM_DTP_MCC Logs) and included here for reference.

MCC Training Logs Instructions:

- Consult the METRC Policy & Procedure Manual Table of Contents and Index to determine which documents within the PPM compendium are applicable to you within your role at the METRC Coordinating Center.
- Upon reading and/or receiving training on each applicable document, enter (in writing) the Document ID and version date into the table below and note in the appropriate column your initials and the date that you read the document and/or received the training. Your initials and date are your certification of meeting the training requirement. If you have any questions or concerns, you should seek clarification prior to initialing and dating.
- A member of the MCC Executive Management Team must date and initial in the final column to verify that s/he is in agreement that the training requirement has been appropriately met. His or her initials and date will serve as this verification.
- As documents are revised or newly made available in the PPM, you will be notified so that you can read and receive training as necessary based on your role within the METRC Coordinating Center.
- If your role within the MCC changes over time, it is your responsibility to consult the PPM Index to determine if there are any new or additional applicable documents which are required for your new role.

Completed Training Logs will be maintained in central METRC PPM Training Binder which is stored MCC Administration personnel.

DOCUMENT HISTORY

- **V3, 3/9/2020**
 - Updates: Updated location of PPM on METRC Website; corrected a few typographical errors
 - Dissemination Method: Email Memo
 - Primary Author(s): Lauren Allen, Operations Director
 - Stakeholders Engaged: NA- updates only
 - Formal Review or Approval Process: N/A
 - Name & Role of Trainer: N/A
 - Date & Venue of Training: N/A
 - Who Attended Training: N/A

- **V2, 6/28/2019**

- Updates: Section III, “Policy & Procedure Manual Content Dissemination”, was added; The section “Policy & Procedure Manual Training”, which was previous Section III was made Section IV.
- Dissemination Method: Email Memo
- Primary Author(s): Lauren Allen, Operations Director
- Stakeholders Engaged: NA- updates only
- Formal Review or Approval Process: N/A
- Name & Role of Trainer: N/A
- Date & Venue of Training: N/A
- Who Attended Training: N/A

- **V1, 6/12/2019**

- Updates: N/A
- Dissemination Method: MCC Staff Meeting; Publication to Dropbox
- Primary Author(s): Lauren Allen, Operations Director
- Stakeholders Engaged: Tony Carlini, Director of Informatics; Renan Castillo, MCC Deputy Director
- Formal Review or Approval Process: N/A
- Name & Role of Trainer: Lauren Allen, Operations Director
- Date & Venue of Training: 6/12/2019, MCC Conference Room
- Who Attended Training: MCC Staff, Dr. Bosse