METRC Policy & Procedure Manual

Title: Standard Procedures for Maintaining Site Electronic Regulatory Binders

General Description & Purpose: This document describes the METRC Coordinating Center's standard procedures for organizing and storing the regulatory materials associated with sites' participation in METRC studies.

I. Standards for File Storage and Organization of Site Regulatory Materials

Site regulatory materials are stored in folders on shared METRC Dropbox. These folders constitute the electronic regulatory binders for the sites participating in METRC studies. The MCC study team, usually the Study Manager, will be responsible for setting up the folder structure per the specifications below.

Electronic Regulatory Binder Organization

The main METRC Dropbox Folder is called, "Clinical Site Regulatory Binders". To set up a file storage system for a new study:

- Create a new folder for storing the electronic site regulatory binders. The folder name should be the study acronym if applicable, e.g., "VANCO", or the abbreviated study name, e..g, "Weight Bearing".

- Within the study folder, create a folder for each participating site. The folder name should include the study acronym or 3-letter study code and the site airport code.
    - Examples: VAN Reg Binder- CMC; OUTLET Regulatory Binder_UMD

- Within each site's electronic regulatory binder folder, there should be the following minimum set of sub-folders. Additional folders may be added at the study team's discretion. Each site folder within any given study should be set-up consistently. Required sub-folders:

    - Approval Letters
        - This folder should contain IRB, DoD (if applicable) approval letters. Approval letters for continuing reviews and amendments should also be placed in this folder.
        - The file name should be sufficiently descriptive and should include the date of the approval or the date of expiration. Examples:
            - VANCO_CMC_Initial IRB Approval_10.06.2014
            - Bioburden_UMD_Initial HRPO Approval_exp 20120317
            - PRECISE_MTH_IRB Continuing Review Approval_2018.10.24

    - Initial Regulatory Review Materials

        - This folder should contain all materials submitted to and approved by the local IRB and the DoD HRPO if applicable.
        - Approval letters may also be saved in this folder so long as they are duplicated in the Approval Letters folder.
        - While it is helpful to save files using standard identifiers, descriptive language, and applicable dates, it is only a requirement that approval letters are saved using the naming convention.
        - Non-study-specific documents which must be submitted to the IRB, DOD, or to the MCC as part of certification do not need to be saved in this folder. These documents should instead be saved in the Certification Document Repository. The non-study-specific documents include the following. (*Also see: Policy and Procedures for Certification Document Repository*).
            - CVs or resumes
            - Medical Licenses
            - Human Subjects Training Certificates
            - Good Clinical Practice Training Certificates

    - Certification Materials & Local SOPs
        - This folder should contain all materials submitted to and approved by the METRC Coordinating Center for the purpose of Site Certification.
        - This folder should also contain the site's Certification Approval Letter and the Delegation of Authority Log(s). These approval documents may be duplicated in the Approval Letters subfolder at the discretion of the study team; the approach should just be consistent across sites.

    - Continuing Review & Amendment Approval Materials
        - This folder should contain all continuing review and amendment materials submitted to and approved by the local IRB and DoD (if applicable).
        - Approval letters may also be saved in this folder so long as they are duplicated in the Approval Letters folder.
        - While it is helpful to save files using standard identifiers, descriptive language, and applicable dates, it is only a requirement that approval letters are saved using the naming convention.
        - It is strongly recommended that continuing review materials (and amendments as applicable) are grouped together and saved in a sub-folder indicating the year of the continuing review approval. For example, all materials submitted and approved as part of the 2020 continuing review would be saved in a sub-folder with a title such as: OUT_USF_2016 CR

    - Study Close Out
        - This folder should contain all study close out materials submitted to and approved or acknowledged by the local IRB and DoD HRPO if applicable.
        - Approval or acknowledgement letters may also be saved in this folder so long as they are duplicated in the Approval Letters folder.

II. Procedures for filing Site Regulatory Documents

Method of Receiving Regulatory Materials

Sites' regulatory materials are submitted to the study team at the MCC by direct email or by carbon copying the MCC study team on a regulatory submission to the DoD HRPO (for DoD Sponsored studies). DoD HRPO approval and acknowledgement letters are issued in the form of an email memo which may be converted into a PDF for file storage purposes.

Electronic Filing Procedures

As of the publication date of this document, the following procedures will be used to ensure that all site electronic regulatory materials are filed electronically in a timely manner:

- The MCC study team member (usually the Study Manager) will review and identify the regulatory documents received by the METRC site.
    - If necessary, the study team member will correspond with the site to request clarification, missing documents, etc.
    - The study team member will also track or log the administrative data associated with the regulatory submission in the appropriate place, e.g., the METRC Database Study Local table, etc. (*Also see: Policy and Procedures for Tracking Study Site Approval Data*).

- Once confirmed as complete, the MCC study team member will forward the email, including all attachments, to the central METRC mailbox: regbinder@metrc.org
    - In forwarding the email and attachments, the study team member will provide a brief description of the materials to be electronically filed and brief instructions for where to file them.
    - The study team member will also provide the file name for any document, i.e., approval letter, that should be saved per a required naming convention or per the study team member's preference.
    - Examples:
        - "This is the initial approval for Carolinas Medical Center for the NERVE Study. The approval letter should be saved as NIS_CMC_Initial IRB Approval_20170719."
        - "This is the HRPO acknowledgement memo for Methodist's PRECISE Continuing Review. Please PDF and save in the 2020 CR subfolder in their electronic regulatory binder with the filename PRECISE_MTH_2020 CR HRPO Approval_exp 10.02.2021"

- The MCC Administrative Coordinator or an assigned Research Assistant will be responsible for checking the central mailbox on a prospective basis. Regulatory materials will be filed (i.e., posted to the applicable Dropbox folders) within 2 weeks of receipt (to the central mailbox).
    - If the Admin Coordinator or Research Assistant has any questions, s/he should correspond directly with the study team member.

- Once all regulatory documents have been electronically filed on dropbox, the Admin Coordinator or Research Assistant will reply to the study team member, in the original email message, to confirm that the materials have been filed.

- Finally, the Admin Coordinator will clear the central email inbox and move the emails into an email folder called “Filed Regulatory Submissions”.

Last Updated: June 2019