

METRC Policy & Procedure Manual

Title: Standard Procedures for Obtaining and Distributing DSMB Determination Letters

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General Description & Purpose: This document describes the METRC Coordinating Center's standard procedures for generating the DSMB determination letters, for obtaining appropriate signatures on the letters, and for distributing the letters to the appropriate consortium members.

I. Standard Procedures for Generating DSMB Determination Letters following DSMB Meetings

DSMB Determination Letters are a critical output of the METRC DSMB Meetings. These letters summarize the DSMBs discussion of a METRC study and the Board's determination as to whether the study is safe to continue.

Following a METRC DSMB Meeting, an Associate Director of the METRC Coordinating Center works directly with the METRC Senior Biostatisticians to draft the determination letters. The draft letters are then sent to the Chair of the METRC DSMB for editing, if necessary, and for signature. The finalized and signed letters are sent back to the MCC Associate Director.

While there is no firm deadline for doing so, the letters are typically finalized, i.e., signed and PDF'ed, within 2 weeks of the DSMB meeting during which the determinations were made.

II. Standard Procedures for Filing and Distributing the Determination Letters to Consortium Members

Filing the DSMB Determination Letters

The finalized Determination Letters are filed in the Dropbox folder associated with the specific DSMB meeting; these folders are named using the date of the meeting. The final letters are filed as PDF documents.

Distributing the DSMB Determination Letters

The following steps are taken to distribute the determination letters to appropriate members of the METRC Coordinating Center and the Consortium.

1. An Associate Director of the METRC Coordinating Center sends the final determination letters to the following audiences:
 - Principal Investigators of the studies reviewed. The letters are emailed separately to the respective Principal Investigators, i.e., they are not sent as a batch.

- Appropriate Coordinating Center personnel. The letters are sent as a batch, i.e., as attachments to a single email.
- 2. The Research Assistant responsible for maintaining the Study Materials section of the METRC Website posts the determination letters to the respective study materials pages. S/he then informs the Study Managers that the letters have been posted.

Please note: If this Research Assistant position is vacant, this step will be performed by another member of the Informatics Core. The Informatics Core has overall responsibility for maintaining the METRC Website.

- 3. The Study Managers distribute the determination letters via study memos to sites participating in the studies. The memos are emailed and the determination letters are attached to the email. One memo is sent per study for which there was a determination letter. For example, a REPAIR Study Memo is sent to the REPAIR Sites with the REPAIR DSMB Determination Letter as an attachment.

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