

METRC Policy & Procedure Manual

Title: METRC Site Admission Policy & Processes

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General Description & Purpose: This document describes METRC's processes for admitting new sites into the Consortium.

I. Policy for Admitting New and Returning (*Inactive*) Sites into METRC

Definition of Site Membership in METRC

Site membership in METRC means that the site is actively engaged in METRC-sponsored studies through one or more of the following activities:

- Enrollment and follow-up of study patients
- Involvement in Protocol Committees or the Consortium's Standing Committees
- Participation in writing groups for METRC abstracts or manuscripts
- Participation in ad hoc activities such as the Emerging Investigator Program or Rehabilitation-Engagement activities such as the METRC-sponsored Rehab Symposium

Sites which are engaged in one or more of the above activities, without a lapse in engagement greater than a year in duration, are considered *active* METRC sites. Other sites, regardless of past engagement in METRC, are considered *inactive* sites.

Site Admission into METRC

Sites which are entirely new to METRC, or sites which have been inactive and wish to reengage with METRC, are required to attend the annual METRC Information Meeting which is held in conjunction with the Orthopaedic Trauma Association Annual Meeting. The meeting must be attended by the Site PI or a designated Associate Investigator. Following the METRC Information Meeting, the sites must submit the Application for New and Returning METRC Sites.

The Executive Committee reviews the above-mentioned applications during the November/December meeting and votes to approve or disapprove the new or returning sites. The Executive Committee's decisions are communicated to the sites within a week of the meeting.

II. Annual METRC Information Meeting

Invitation to the METRC Information Meeting

Sites which are entirely new to METRC and which express interest in joining the Consortium over the course of the year are automatically invited to attend the METRC Information Meeting.

Within 2 months of the meeting date, the Clinical Chair of the Consortium and a member of the MCC Executive Management Team review all METRC sites and determine which inactive sites should be invited to the METRC Information Meeting. Individual invitations are then sent to the PIs of these sites. The invitations are sent by email from a member of the MCC. The emails include an attached formal letter/invitation from the Clinical Chair of the Consortium and the Director of the Coordinating Center.

METRC Site Admission Committee

The Annual METRC Information Meeting will be hosted by an Ad Hoc Committee where the membership minimally includes:

- Clinical Chair of the Consortium
- Representative from the Coordinating Center Executive Management Team
- Representative from the Executive Committee who is also a PI for his or her site
- Representative from the Implementation & Quality Committee

METRC Information Meeting Agenda

The purpose of the METRC Information Meeting is to provide the PIs of new or returning sites with adequate information about METRC and the requirements for participating sites such that s/he can make an informed decision regarding his or her site's ability to successfully contribute to the Consortium.

The agenda for the METRC Information Meeting will minimally include the following components:

- Overview of METRC history and organization
- Overview of the leadership and infrastructure required for a site to be successful within METRC
- Overview of the performance and data quality expectations for METRC sites
- Overview of contracts and payments to sites
- Overview of the many ways a site (or PI) can get involved in METRC
- Question & Answer session

Other topics may be added to the agenda as appropriate. For example, it may be worth briefly mentioning studies open to site participation.

III. Policy Exceptions

METRC site membership is inextricably linked to the leadership and engagement of the site Principal Investigator. There are 2 specific scenarios for which the above-described policy and procedures do not apply to the site and/or PI:

- 1) If the PI of a METRC site is leaving his or her institution, and the site is active within METRC and in good standing, s/he may designate another investigator at the site as the new PI. The site's status as an active site continues, assuming the new PI accepts his or her role and meets all expectations for site/PI performance.
- 2) If the PI of a METRC site is leaving his or her institution and going to another institution which is not an active member of METRC, s/he may establish the new institution as an active METRC site.

This assumes the PI in the scenario is in good standing with METRC and that s/he understands what is required for a site to successfully contribute to the Consortium.

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