



METRC Publications and Presentations Policy Guide

(v. 4)

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1. Charge of the METRC Publications Committee

The Publications (Pubs) Committee provides guidance and oversight relative to reporting study data and assures that study reports have expert input, a high standard of scientific quality, responsible conclusions, and sound interpretations and fulfill the overall objectives of the Major Extremity Trauma and Rehabilitation Consortium (METRC). The charge of the Pubs Committee is to

- Develop guidelines for publications regarding review and approval of manuscript proposals, assignment of tasks in analysis and writing, review of manuscripts, authorship policy, and other issues related to publications.
- Make recommendations to the Executive Committee about topics for publications.
- Make recommendations to the Executive Committee about topics for presentations at national and international meetings.
- Make recommendations concerning the priority of manuscripts and presentations.
- Review manuscripts prior to journal submission and review presentations prior to conference submission.
- Mediate and settle all disputes and conflicts among study investigators over publication or presentation priorities, authorship, and any other issues related to publications or presentations. If Pubs Committee's deliberations fail to resolve such a dispute, the dispute will be submitted for resolution to the Executive Committee, excepting those members with a conflict of interest.
- Prepare and maintain a list of papers planned for publication and a list of approved METRC publications, which shows the status of each manuscript from initiation through publication.

The Committee will meet monthly or as need arises via conference call.

2. Goals

- To promote timely, scientifically accurate, and high-quality presentation and publication of findings from METRC studies.
- To support broad and equitable participation by METRC investigators in presentations and publications.
- To define a set of equitable guidelines to determine authorship and the order in which authors are listed.
- To review and select topics for publications and presentations, invite or assign authors to writing groups, set priorities for publications and presentations, and monitor progress of publications and presentations.
- To provide editorial support and timely review for presentations and publications.
- To defend the academic freedom of METRC investigators collectively to publish results emanating from the METRC studies, while providing limitations on publication of results from any one center that could threaten the integrity of collective data.

3. Scope of this Document

These guidelines apply to the following:

- Original manuscripts (including methodology, validation, and surgical approaches), abstracts (for publication or presentation), letters to the editor, meeting proceedings, and extended abstracts that include data collected as part of METRC.
- Other publications arising from METRC core, main, sub studies, and pilot or feasibility studies.
- Review articles that include original METRC data not previously published.

The Committee reserves the right to amend the Publications and Presentation Policy Guide as necessary to clarify its intent. Any changes to these guidelines will be reported to the Executive Committee with a request for feedback.

4. Publications Committee membership

The Pubs Committee consists of the following:

- a chairperson appointed by the Executive Committee
- Principal Investigators (PIs) from at least five different clinical sites (from one another as well as from the chairperson's site)
- A PI from at least one Military Treatment Facility (MTF) clinical site
- At least 3 rehabilitation investigators
- The Principal Biostatistician of the METRC Coordinating Center (MCC)
- The Department of Defense (DOD) Program Officer of METRC
- The Consortium Chair (*ex officio*)
- Consortium Vice-chair (*ex officio*)
- The Director of MCC (*ex officio*)
- The Deputy Director of MCC (*ex officio*)
- Emeritus Consortium Chair (*ex officio*)
- Emeritus Director of the MCC (*ex officio*)
- an Associate Director at MCC (*ex officio*), who serves as MCC point person for the committee.

The Committee will be staffed by the MCC's editorial assistant. Each member, including *ex officio* members, has one vote.

The chairperson serves for a three-year term, and the other members (other than *ex officio*) serve for staggered two-year terms.

The Principal Biostatistician of the MCC, the *ex officio* members, and the DOD Program Officer of METRC serve for the duration of the core funding from the DOD. The number of consecutive or interrupted terms that a chairperson or other elected member may serve will not be limited. If a member is an author on a presentation or manuscript or otherwise has a conflict of interest, that member will recuse himself/herself from the Committee's review of the proposal or manuscript or presentation.

5. METRC Study Types

The Consortium conducts the following three types of studies:

- **Core Studies** address primary research questions of direct interest to the Department of Defense (DOD) and are funded by DOD through core METRC funding—METRC is the prime grantee or contractor on such as study. The PI comes from the MCC or a METRC clinical site. Examples of core studies are those funded by one of the three METRC Consortium Awards (“METRC 1”, “METRC 2”, “METRC 3”).
- **Main Studies** address the objectives of METRC, are supported by METRC infrastructure, but require funding in addition to that available through core support of the consortium, such as from NIH or another agency. The MCC may be either the prime grantee/contractor *or* the study may receive support through a subcontract from the prime grantee/contractor for the study (typically the Study PI’s institution). The PI can be an investigator at one of the clinical sites or from the MCC. Examples of main studies are those funded through the Peer Review Orthopaedic Research Program (PRORP) (i.e., POVIV, REPAIR, NERVE), NIH (i.e., STREAM), and PCORI (i.e., PREVENT CLOT).
- **Substudies** are subordinate to a core *or* main METRC study and address a secondary objective not originally stated in the detailed study protocol of the core or main study. Substudies may or may not involve additional data collection. The PI may be either an investigator at a clinical site that is a participant in the parent study or a member of the MCC. A substudy will use central resources of METRC such as those provided by the MCC only when supported by funding for the substudy. A substudy should not interfere with or duplicate activities of a core or main study, or an existing substudy.

6. Types of METRC Publications

Main Results papers	Arise from core or main studies and address the primary aim of these studies (per the study protocol). If the study has more than one primary aim, the Protocol Committee will identify the primary report to be generated from the study.
Protocol papers	Outline the protocol for a core or main study, and should be referenced in all other reports that come out of such a study.
Secondary papers using data from one study	Include papers that address the secondary aims of a core or main study and substudies unrelated to secondary aims that use data from a single study. Use of data for these papers must be approved by the study PI.
Secondary papers that pool data across multiple studies	Include substudies that are unrelated to primary and secondary study aims that involve pooling data across multiple METRC core and/or main studies. These projects must be approved by the Science Committee

	and use of data must be approved by the PI of each contributing study.
Tertiary papers	These papers include: (1) substudies using data from METRC core or main studies to demonstrate methodology, rather than having a direct applicational status (for example, using study data to help illustrate a new means of statistical analysis); (2) substudies using data from a single METRC site; and (3) studies resulting from surveys of METRC sites.
Other	Letters to the editor, review articles

7. Writing Groups and Authorship

7.1 Writing groups

All METRC papers must have a writing group with a designated chair, which is reviewed and approved of by Pubs Committee.

The Writing Group Chair

The study PI will be the writing group chair for main results papers and protocol papers. For secondary papers, the writing group chair may be a member of the Protocol Committee. The same is true for tertiary methodology papers, or otherwise to be determined on a case-by-case basis by the Pubs Committee. If no one from the Protocol Committee is interested in serving as chair, the MCC will extend the invitation to investigators at participating centers.

Writing Group Membership

Once the writing group chair has been identified, an invitation will be sent by the MCC to members of the Protocol Committee(s) to join the writing group. The writing group chair may recommend other individuals to be on the writing group, including fellows and/or research assistants. The writing group may include a minimum of three clinical investigators and a minimum of three members of the MCC, and a maximum each of five clinical investigators and five members of the MCC. Concerted effort will be made to balance the number of MCC authors with the number of clinical investigators. More specific guidelines for writing group membership are outlined in [Appendix A](#). If the writing group chair feels there should be either fewer or more authors, or that an imbalance in the number of investigators and MCC authors is justified, he or she may submit an exemption request to Pubs Committee. Opportunities for writing group membership will be communicated clearly to all possible appropriate potential contributors. Fellows and residents may participate as members of writing groups as outlined below (see [7.5](#)).

Pubs Committee will review writing group membership to ensure compliance with current policies and guidelines. It may propose additional or alternate writing group members. Writing groups must be approved by the Committee before any work is done on a manuscript.

Naming Authors

The following points apply when modified corporate authorship is used for a publication or presentation:

- The writing group will be listed as authors on the byline of the paper.
- Order of authorship: The chair of the writing group will propose authorship order to Pubs Committee as agreed upon by the writing group. The Committee may amend the order of authorship to recognize an exceptional contribution to the study or the manuscript by an individual. For all manuscripts, factors to be included in decisions about order of authorship are contribution to concept, design, and analysis; role in drafting the article or revising it critically for important intellectual content; completeness and integrity of the data and specimens from the investigator's site; and leadership role.
- Unless he/she delegates otherwise, the chair of the writing group will be the first author. Investigators who perceive inequities in authorship or other problems relating to authorship should discuss these concerns with Committee Chairperson; if the difficulty cannot be settled in this informal manner, the concerned investigator should submit a letter to the Committee Chairperson outlining the problem. The document will be reviewed and discussed by the Committee, and a written reply will be made to the investigator. If Committee deliberations fail to resolve such a dispute, the dispute will be submitted for resolution to the Executive Committee, excepting those members with a conflict of interest.

7.2 Authorship criteria

Authorship criteria is based on “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication (Updated October 2008) Publication Ethics: Sponsorship, Authorship, and Accountability,” available at http://www.icmje.org/urm_main.html. Individuals meeting the following criteria will be listed as authors on METRC publications:

- 1) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- 2) Drafting the work or revising it critically for important intellectual content; AND
- 3) Final approval of the version to be published; AND
- 4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Expertise (e.g., statistical, virology, or pathology) that relates directly to the conduct of the study is an additional criterion for authorship. Provision of study material or patients; data collection and assembly; administrative, technical, or logistic support; and obtaining funding do not necessarily merit authorship but should be considered on a case-by-case basis, especially when other contributions are included; see also section [7.3](#) below and the [Corporate Authorship Framework, Appendix B](#). Honorary authorship will not be considered.

Acknowledgements

To ensure transparency for the process of manuscript development, individuals who make significant contributions to the paper but who do not meet the criteria listed above should be included in an acknowledgement. This should include, for example, the Data Safety

Monitoring Board in a protocol paper. For other manuscripts, the lead author and writing group may consider who should be acknowledged on a case by case basis. Furthermore, any individual who is identified by a site PI as a study contributor, but who declines authorship, may instead be acknowledged; the opportunity to identify as such will be included on the corporate author survey.

7.3 Authorship format by type of report

Main results papers: These papers fall under the corporate authorship policy. There are no byline authors; rather papers are authored by “METRC.” Corporate authorship is inclusive. Corporate authors include (1) individuals involved in writing the grant, protocol and/or measurement plan; (2) individuals who made scientific contributions in developing or operationalizing an aspect of the study or provided high level managerial work for the study; and (3) individuals who participated in study development, maintenance, enrollment follow-up, data management and analysis as part of their job responsibilities.

Protocol papers and secondary papers from one study: These papers fall under the modified corporate authorship policy (i.e., the byline reads Author 1, Author 2, Author 3 [...] “and METRC”). Corporate author lists for these papers will be restricted to the study team and key individuals at participating centers. Corporate authors will include (1) individuals involved in writing the grant, protocol and/or measurement plan; and (2) individuals who made scientific contributions in developing or operationalizing an aspect of the study or provided high level managerial work for the study. Protocol papers should also include Protocol Committee members, key site personnel, and other individuals critical to study development.

Secondary papers that pool data across multiple studies: These papers also fall under the modified corporate authorship policy (i.e., Author 1, Author 2, Author 3 [...] “and METRC”). Corporate author lists for these papers will be minimal to include only individuals involved in writing the grant, protocol and/or measurement plan for the study from which the data was drawn.

Tertiary Papers: These papers include: (1) studies using data from METRC core or main studies to demonstrate methodology, rather than having a direct applicational status (for example, using study data to help illustrate a new means of statistical analysis); (2) studies using data from a single METRC site; and (3) studies resulting from surveys of METRC sites. These papers do *not* fall under the corporate authorship policy because the work is sufficiently separate from the main study and its aims and results. However, because the paper uses METRC data, acquired through METRC funding, “and METRC” should be added at the end of the author byline. Any such paper proposal should be approved by protocol committee and then sent to publications committee for approval and review of the writing group.

In all cases, writing group opportunities will be offered to individuals meeting criteria for authorship as outlined above.

For corporate and modified corporate authorship papers, an appendix listing all participating

investigators will be included in the manuscripts using the format provided in Appendix A.

See also the [Corporate Authorship Framework, Appendix B](#).

7.4 Determining Corporate Authorship

PIs at participating centers will be asked by the MCC to identify corporate co-authors at their site. Corporate authors may include co-investigators or research coordinators so long as the individuals meet authorship criteria. The Pubs Committee chair will review authorship lists to ensure equity across centers as necessary.

To be included as corporate authors, identified individuals must critically review the manuscript drafted by the writing group and return a signed authorship form ([Appendix C](#)) to verify that authorship criteria (see section [7.2](#)) are met. (See also [10.2](#).) Individuals who do not respond to the authorship survey or confirm they meet all authorship criteria by the pre-specified deadline will not be included as an author.

Corporate authors are listed in an appendix in the manuscript; in this appendix, participating centers are listed in alphabetical order. Per each center, the PI is listed first, followed by contributing investigators in alphabetical order, and then by research assistants in alphabetical order. No more than two degrees per author will be listed; authors will be asked on the authorship form ([Appendix C](#)) to prioritize highest academic degrees and/or key licenses (like RN), and refrain from listing fellowships and similar designations.

Corporate authorship will not be offered to sites that do not enroll any patients. An exception may be made if an investigator at a site with no enrolled patients made meaningful contributions to the project in some other way. In this case, an appeal should be made to the Publications Committee.

Tertiary methodology papers, which may use METRC data to illustrate a new method or measure but are not related to the study's aims or outcomes, do not include corporate authors. Such papers need to be proposed first to the Protocol Committee, then its writing group must be approved by Pubs Committee. Pubs Committee must also approve the manuscript before submission. Survey papers also follow tertiary paper protocol.

7.5 Authorship Guidelines for Fellows and Residents

To receive author credit, fellows and residents must meet authorship criteria as listed in [7.2](#). Fellows and residents can be included in the writing group and listed as a byline author on pre-specified METRC papers, but protocol committee members and METRC site investigators have first right of refusal.

Fellows and residents can be first author on papers they propose that are approved by the Publications Committee. These cannot be primary or anticipated secondary papers but rather new ideas typically involving data across multiple METRC studies, or otherwise on a case-by-case basis to be approved by Pubs Committee. Fellows and residents can be a byline author on secondary papers provided their membership of the writing group is approved, per standard practice described in [7.1](#).

8. Proposal of topics and review of proposed topics

The MCC will keep a list of topics proposed for manuscripts and will maintain a list of approved topics and their status.

Any member of the Consortium may propose a manuscript.

- Paper ideas using data from one study must be approved through that study's Protocol Committee.
- Paper ideas pooling data from multiple studies require approval by each study's PI and the Science Committee.

The MCC will distribute a copy of the proposals to members of the Committee with a deadline for return of comments (or will schedule a conference call to discuss them). The Committee will approve the final writing group membership and the writing group chair as outlined in [7.1](#).

Criteria for judging proposals:

- scientific merit of the hypothesis or aim of the proposal
- availability of appropriate data to address the hypothesis or aim

If overlap in content exists between or among proposals, the Committee will either eliminate overlap or consolidate the proposals.

9. Acknowledging METRC in publications and presentations

All METRC manuscripts and presentations must include an acknowledgment of DoD Core METRC funding, with specific grant numbers, other supporters or organizations. Where applicable, all other funding sources must also be listed with specific grant numbers, other supporters or organizations.

If METRC-funded resources (including personnel) are used during manuscript development, but the study itself does not use METRC data, the lead author should submit the abstract to Pubs Committee for review. The committee will determine if METRC should be acknowledged and how to do so on a case-by-case basis.

Note that as of the start of the METRC3 grant, METRC's full name spells out "Major Extremity Trauma and Rehabilitation Consortium" rather than "... Trauma Research Consortium." Papers using older grants may still refer to METRC by the older name. Beginning January 1, 2020, all papers should be sure to switch to referring to METRC using the new "Rehabilitation..." branding.

10. Manuscript development and review

10.1 Writing the Initial Draft

Target Journal

The writing group determines the target journal and is responsible for drafting the manuscript according to journal-specific formatting guidelines. The Pubs Committee can recommend a different journal to ensure appropriate readership and maximize potential for acceptance. In cases where the writing group and the Committee are unable to agree on a target journal, the Executive Committee may choose to adjudicate.

“Fast Track” Manuscripts

When abstracts are accepted for presentation at the Orthopaedic Trauma Association Annual Meeting, sometimes the OTA invites the authors to submit their manuscript for “fast-track” publication in the *Journal of Orthopaedic Trauma*. If the authors agree, this means when the manuscript is close to completion, the authors send a draft to JOT for right of first refusal of the manuscript. This assures quicker processing when the final manuscript is submitted later, but means the authors are committing to publishing with the JOT early in the process of developing the manuscript.

In this and all similar cases, the writing group must consult with Publications Committee before agreeing to “fast tracking” their paper with a journal.

Self-Plagiarism

The writing group will ensure the paper avoids self-plagiarism:

- Where appropriate, authors should cite prior publications, particularly protocol papers, which use similar verbiage.
- Methods sections may use duplication of text, but if in doubt, the authors should still cite protocol papers where the text originates.
- If the authors deem repetition is necessary in the introduction or discussion of an article, they will evaluate the text carefully to avoid copyright infringement with prior articles on the same study.

Manuscript Development

Manuscripts will be prepared in full collaboration with the writing group as outlined here. The chair of the writing group is responsible for assigning tasks to other members of the writing group and for overseeing the completion of these tasks on schedule.

All data analysis will be performed with the involvement of a qualified statistician either at the Coordinating Center or at one of the METRC Sites.

If a writing group does not complete its work or fails to meet timeline milestones, the Committee may reassign the roles of chair or select new writing group members. This exigency may be exercised if no draft is produced within three months of the availability of a clean data set at the discretion of Pubs Committee.

If, during the course of work on a manuscript, the analysis is found to be too broad for a

single manuscript, the writing group may suggest that the data would be more suitable for more than one manuscript. The writing group must notify the Committee that they plan to narrow the scope of the manuscript.

Members of the writing group will use a cloud-based sharing tool to save manuscript drafts and edits, which will be managed by a member of the writing group at the MCC (unless otherwise specified).

References should be inserted into the manuscript using comment boxes. The editorial assistant at the MCC will incorporate these references into the METRC Ref Works library and will be responsible for generating the paper references once the draft is complete. If the writing group chooses to not use the editorial assistant's aid, the reference list will be generated by the lead author or delegated member of the writing group at the end of the drafting process.

10.2 Incorporating Edits from Corporate Authors (for applicable papers)

Once the manuscript is completed, the writing group will forward it to the MCC editorial assistant or point person. The editorial assistant will proofread and distribute the manuscript to corporate authors for review and feedback, alongside the authorship form, usually via REDCap Survey.

Feedback and edits from the corporate authors received by a specified deadline will be compiled by the editorial assistant and then shared with the lead author and other members of the writing group. The writing group chair will work with the writing group to address the feedback and revise if necessary, before sending the draft to Pubs Committee for approval.

10.3 Manuscript Review and Submission

Pubs Committee will provide editorial review and approval for all manuscripts. The writing group chair will forward final drafts, which have been read and approved of by all members of the writing group and, if applicable, corporate authors, to the Committee in care of the MCC, usually to the editorial assistant. The editorial assistant will distribute the draft to the Committee and solicit comment and approval, normally within one–two weeks. The review deadline is not to exceed four weeks. The editorial assistant relays Pubs Committee feedback to the writing group.

The writing group is responsible for addressing Committee concerns and making further edits if necessary. If requested revisions are substantial, as determined by the Committee, corporate authors will again be asked to review and approve the revised manuscript. Otherwise, corporate authors do not need to review edits post-Committee review. A final copy of the manuscript will be sent to them for their records.

Submission

Once the manuscript is approved by the Committee, the writing group is responsible for ensuring the manuscript is submitted to the target journal. The group chair may choose to use the MCC editorial assistant's help with proofreading, formatting, and submitting the document; in this case the group's chosen corresponding author should coordinate with the

editorial assistant so the assistant can submit the manuscript in the author's name. If the writing group chair opts not to delegate editing or submission to the editorial assistant, the chair will update the Pubs Committee via the editorial assistant on the manuscript submission's progress.

The writing group is responsible for addressing peer review comments and editing the manuscript for resubmission if necessary. In the rare event that substantive changes are required, corporate authors will again be asked to review and approve the edits, and the revised manuscript again will be vetted through the Publications Committee for approval before revisions can be submitted. The writing group is responsible for requesting any deadline extensions that these extra review processes may require.

11. Publications priorities

No investigator may jeopardize the publication of METRC study results in a peer-reviewed journal by releasing or presenting data prematurely. Local press releases are to be timed to coincide with publication of manuscripts and must respect any applicable publication embargoes. No individual site will be permitted to publish site-specific METRC results without the approval of the Executive Committee.

12. Presentations, abstracts, and letters to the editor

12.1. Conference Abstracts and Presentations

Abstracts using METRC data submitted to national and international meetings must be approved by the Publications Committee according to the following procedures outlined below. The MCC will circulate reminders about major conference (e.g., OTA, AAOS) abstract and Pubs Committee deadlines to prospective authors.

The writing group chair/lead author will submit a proposal to the Publications Committee describing the abstract objective(s), the requisite study data, and a preliminary analysis plan. Proposals should be submitted to the MCC point person two months prior to the abstract deadline.

Pubs Committee will review proposals during their regularly scheduled meetings or as needed, and will work with the MCC to allocate data analysis resources and assist with forming writing groups if necessary.

Lead authors must also submit the full abstract (with a complete statistical analysis and write-up in the required format) to the Pubs Committee via the MCC editorial assistant or point person for final approval. This must be in advance of the conference's submission deadline. Pubs committee will establish two deadlines for this process:

- a. Two weeks prior to the conference's submission deadline is the "early approval"; pubs will return comment within the week of receipt and the writing group will have more time to revise the abstract.

- b. A final pubs-approval deadline a few days prior to the conference submission deadline. The Committee will establish the exact deadline on a case-by-case basis; it may be as long as a week before if Pubs is unable to call an ad hoc committee to discuss the abstract. Pubs Committee will give comment and approval or disapproval one to two days prior to the conference submission deadline. This gives writing groups more time to finish their initial draft but must be aware that they must make any requested changes within a much shorter period of time before submission.

Abstracts submitted after the second due date will NOT be reviewed or approved of by the Committee.

The Committee will review the abstracts either during regularly scheduled monthly meetings or will call a special meeting in order to comply with deadlines. The Committee will 1) approve as written; 2) approved with revisions; or 3) disapprove (requiring further discussion).

The MCC editorial assistant will compile and relay Committee feedback to authors prior to the deadline in accordance with other deadlines set by Pubs Committee.

The lead author is responsible for confirming revisions to the abstract with the rest of the writing group before submission to Pubs Committee, particularly ensuring the writing group's statistician has been given ample time to review and approve the abstract. The lead author should use the Abstract Submission Checklist ([Appendix D](#)) to ensure the abstract has gone through correct procedures before submission to the Pubs Committee.

Where possible, such as with the Orthopaedic Trauma Association Annual Meeting, Pubs Committee prefers that all METRC conference abstracts are submitted centrally from the MCC. Usually the editorial assistant completes this task. A generic METRC account for submission will be created, linked with authorship@metrc.org or another metrc email address. This ensures consistency in applying corporate and modified corporate authorship to the writing group bylines. *This means that the lead author must submit the final, revised abstract to the MCC editorial assistant or other point person before close of business on the conference submission due date.* Abstracts that are sent in too late may not be submitted.

If a generic submission account cannot be created for a conference, lead authors or another presenter are responsible for submitting the abstract to the conference on time.

Abstracts submitted to more than one meeting do not require additional review by the Publications Committee, unless there are substantive changes between the submissions, including changes due to new data coming in. In this case, the Committee Chair and the MCC point person will consider the situation to determine whether full committee review is necessary.

Final versions of posters and podium papers of already-accepted abstracts do not require review by the Publications Committee, unless the abstract was submitted without results (see below).

Submitted Abstracts without Results

If an abstract does not contain results at the time of Pubs Committee approval, and it is accepted for presentation by the conference, the authors must resubmit the paper to the Publications Committee for review when results come in, prior to submitting the final version of the presentation with results to the conference.

Abstract Authorship

Presentations and abstracts use modified corporate authorship (exceptions should be considered on a case-by-case basis). Writing groups are formed in accordance with the authorship guidelines (see section [7.1](#)). The abstract will include acknowledgment of DoD and other funding, where applicable.

Abstracts that do not use METRC data but use METRC resources (e.g., METRC grant-funded personnel) to conduct the project do not need to include METRC as an author. However, if the conference accepts the abstract, it should acknowledge METRC on the poster or presentation (see also section 9). These projects require review by the Committee. Potential cases will be reviewed by the Pubs Committee chair and the MCC point person to determine if a particular abstract needs to be reviewed in this way.

Abstracts for breakout sessions do not need to include METRC as an author. However, if accepted, and the presenters use previously unpublished or unrepresented METRC data, the presentation(s) will need to be reviewed and approved by the Publications Committee, and METRC should be acknowledged in the presentation.

Presentation Format

All presentations of new material using METRC data and/or resources must be presented using the METRC-branded PowerPoint template. Authors should not use their own site's template or logos. If they do not have the template, authors should contact the MCC to get it.

12.2. Other Presentations and Letters to the Editor

Committee approval is not required for local presentations and accompanying syllabus material (e.g., medical school lectures, continuing education courses, grand rounds lectures, research seminars, etc.). Investigators are encouraged to consult the Committee Chair when questions about the propriety of a local presentation arise. If the Chair cannot address such questions readily, the issue will be considered by the entire Committee (via conference call or written communication).

Letters to the editor are approved according to the same process used for abstracts.

13. Reprints and postings to the METRC website

Alongside their citation, published METRC manuscripts will be linked to on the METRC website. Abstracts and slide material or posters prepared for presentation at national or international meetings will also be posted.

14. Public Access Compliance

METRC's primary source of funding, the Department of Defense, does not require study papers to be publicly accessible, so at this time, METRC authors as a rule do not make its papers open access. If a particular study is funded by NIH or another Federal funding site that does require public access as a condition of the funding, METRC members will comply with the NIH public access policy (including if the Department of Defense changes its policy). Usually in this case, all the authors of a relevant study need do is comply with the journal's and the NIH's requests for any information they need, and the journal will ensure the article will be archived on PubMed Central (<http://www.pubmedcentral.nih.gov/>). If for any reason an author group wishes to make a paper available on PubMed Central when it would not be by default, the authors must contact the journal for permission to have it archived, per standard PubMed Central procedures.

Defining the METRC Research Group

For Papers Arising from Specific Studies:

The Writing Group will typically consist of the Principal Investigator (PI) of the study followed by members of the Protocol Committee (subject to authorship criteria listed in the Publications and Presentations Guidelines). The exact composition will be determined by the Study PI in collaboration with the Publications Committee, in accordance with the Policy.

Participating Clinical Centers: For each center participating in the study, the PI and Co-PI will be listed together along with the Associate Investigators and/or research associates identified by the site as having a significant role in the study.

The METRC Coordinating Center: The MCC Lead Investigator for the study, the Project Director, the Director of the Biostatistics and Informatics Core, the Principal Statistician, and other investigators of the MCC who meet the authorship criteria, subject to review by the Publications Committee.

Acknowledgements: Others, such as the Data Safety Monitoring Board, can be acknowledged as appropriate.

For Publication of a Study Protocol or Papers not tied to any Specific Study:

The Writing Group: The exact composition will be determined by the investigator taking the lead in writing the manuscript in collaboration with the Publications Committee and in accordance with the Policy. For Study Protocols, the writing team will typically consist of the protocol Committee (subject to authorship criteria listed in the Policy).

METRC Core Clinical Centers: For each center participating in the study, the PI and Co-PI will be listed together with the Associate Investigators and/or research associates identified by the site as having a significant role in the study.

METRC Satellite Centers: For each satellite METRC center (listed alphabetically) the PI will be listed together with any additional Associate Investigators identified by the site as having a significant role in writing the given paper. Only satellite centers who are actively enrolling patients into one or more METRC studies will be listed.

The METRC Coordinating Center: The Director and Deputy Director of the MCC, the Project Directors, the Director of the Biostatistics and Informatics Core, the Principal Statistician, the Principal Economist and other investigators of the MCC who meet the authorship criteria subject to review by the Publications Committee.

Acknowledgements: Others, such as the Data Safety Monitoring Board, can be acknowledged as appropriate.

METRC Authorship Framework

Main results papers: These papers fall under the corporate authorship policy. There are no byline authors; rather papers are authored by “METRC.” Corporate authorship is inclusive. Corporate authors include (1) individuals involved in writing the grant, protocol and/or measurement plan; (2) individuals who made scientific contributions in developing or operationalizing an aspect of the study or provided high level managerial work for the study; and (3) individuals who participated in study development, maintenance, enrollment follow-up, data management and analysis as part of their job responsibilities.

Protocol papers and secondary papers from one study: These papers fall under the modified corporate authorship policy (i.e., the byline reads Author 1, Author 2, Author 3 [...] “and METRC”). Corporate author lists for these papers will be restricted to the study team and key individuals at participating centers. Corporate authors will include (1) individuals involved in writing the grant, protocol and/or measurement plan; and (2) individuals who made scientific contributions in developing or operationalizing an aspect of the study or provided high level managerial work for the study. Protocol papers should also include Protocol Committee members, key site personnel, and other individuals critical to study development as outlined in the framework below.

Secondary papers that pool data across multiple studies: These papers also fall under the modified corporate authorship policy (i.e., Author 1, Author 2, Author 3..... “and METRC”). Corporate author lists for these papers will be minimal to include only individuals involved in writing the grant, protocol and/or measurement plan for the study from which the data was drawn.

Tertiary Papers: These papers include: (1) use data from METRC studies to demonstrate methodology, rather than having a direct applicational status (For example, using study data to help illustrate a new means of statistical analysis); (2) studies using data from a single METRC site; and (3) studies resulting from surveys of METRC sites. These papers do *not* fall under the corporate authorship policy because the work is sufficiently separate from the main study and its aims and results. However, because the paper uses METRC data, acquired through METRC funding, “and METRC” should be added at the end of the author byline. Any such paper proposal should be approved by protocol committee and then sent to publications committee for approval and review of the writing group.

In all cases, writing group opportunities will be offered to individuals meeting criteria for authorship as outlined above.

[See Table on the next page for summary]

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	Tertiary Methodology papers that use study data and Single-Site Substudies	Secondary papers that use study data (e.g., papers that pool data across multiple studies)	Study Protocols and all papers coming out of a particular study (e.g., secondary aims; secondary analyses using data from one study)	Main results papers
Criteria for corporate authorship	N/A	Involved in writing the study grant, protocol, and/or measurement plan....	...plus EITHER scientific contributions in developing or operationalizing an aspect of the study. OR High level managerial work for the overall study...	... plus participated in study development, maintenance, enrollment, follow up, data management, and analysis as part of job responsibilities.
Authors	<ul style="list-style-type: none"> - Writing group determined on case by case basis and approved by Pubs Comm - "And/or METRC" (but no corp author listing) 	<ul style="list-style-type: none"> - Study PI - Study Co-PI - Other Key Investigators - MCC PI - Project Director - Study Statistician 	<ul style="list-style-type: none"> - Study PI/Co-PI - Other Key Investigators - MCC PI - Project Director - Study Statistician - Protocol Committee Members - Site PIs - Key RCs/staff at PI site - Study Manger - Study analyst - Other MCC faculty 	<ul style="list-style-type: none"> - Study PI/Co-PI - Other Key Investigators - MCC PI - Project Director - Study Statistician - Protocol Committee Members - Site PIs - Key RCs/staff at PI site - Study Manger - Study analyst - Other MCC faculty - All participating site AIs and RCs - Other MCC staff (e.g., IT staff, RAs) - Staff with substantial involvement in conducting lab work, building infrastructure, etc.

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METRC Authorship Form

Please download and read the linked manuscript FIRST, then complete this survey. You will NOT be able to access the manuscript once you click "submit." Note that reading the manuscript and responding to this survey fulfills authorship criteria 2 and 3 listed below. You may offer revisions and suggestions in the comment section below.

Title: [title of manuscript]

Authorship: [Modified Corporate/Corporate]

Writing Group: [names of writing group members]

I confirm that I meet ALL FOUR of the following authorship criteria:

- (1) *Substantial contributions to the conception **OR** design of the work; **OR** data acquisition or analysis, **OR** interpretation of data for the work; **AND***
 - (2) *Drafting the work or revising it critically for important intellectual content;* **AND***
 - (3) *Final approval of the version to be published;* **AND***
 - (4) *Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.*
- **I meet all four author criteria and wish to be listed as a corporate author.**
 - **I do not meet all four author criteria, but I did contribute to the study such that I should be acknowledged as a non-author contributor.**
 - **I do not meet all four criteria, and/or for other reasons I do not wish to be listed in this paper at all (do not fill out the rest of this form).**

Comments on the paper, if any. These will be shared with the writing group and applied if possible to the manuscript:

Contributions to the project (i.e., your role, e.g., drafting, enrollment, interpretation, patient interaction, etc.):

Name and degree(s) as you would like them to appear in the authorship listing. Please limit to your two highest academic degrees or significant licenses (e.g., RN); do not include fellowships or military rankings, etc.: _____

METRC Site Affiliation(s) at time of study: _____

If your site affiliation since changed and is a METRC site, indicate your new site here:

If your current site affiliation is at a non-METRC site, type it here: _____

Conflicts of interest specific to this paper (apart from the grant(s) which funded the study):

No Yes

If yes, list them: _____

I certify the above to be true, to the best of my knowledge.

Signature: _____ Date: _____

If you have any difficulties with or questions about this survey, email ddrye4@jhu.edu.

METRC Conference Abstract Submission Checklist

- Submit a proposal to the Publications Committee describing the objective(s) of the abstract, the requisite data sources, and a preliminary analysis plan.**

Be sure to identify the writing group on the proposal form. All abstracts must have a named writing group to include a lead author + investigators from the appropriate protocol committee(s) and the MCC in accordance with the current guidelines:

A minimum of 3 clinical investigators and 3 members of the MCC and a maximum of 5 clinical investigators and 5 members of the MCC. A request for exemption should be made in circumstances where the lead author feels there should be fewer or more authors.

The publications committee will help with finalizing writing groups if you are unsure who to include.

- Work with the writing group and the MCC to conduct the analysis and write the abstract.**

Prior to submitting the abstract to the Publications Committee for approval, the Coordinating Center must confirm that the abstract has appropriate statistical review and input.

- All writing group members must approve the abstract prior to submitting to the Publications Committee.** The lead author should check, per each submission to a conference, to be sure all writing group members approve of the abstract prior to submission, and that the abstract author listing is complete and correct.
- Submit a full abstract (with complete statistical analysis and write up) to the Publications Committee for review.**
- Submit Publications Committee approved abstract by the conference deadline.**

Please e-mail Lisa Reider (lsemani1@jhu.edu) with any questions you may have.