CHAPTER 8

PUBLICATIONS, ABSTRACTS AND PRESENTATIONS

8. PUBLICATIONS, ABSTRACTS AND PRESENTATIONS

8.1. Policy Statement

Research activities of the BMT CTN are intended to contribute knowledge to the field of hematopoietic cell transplantation. Definitive contributions are made through publications in peer-reviewed literature. Abstracts, public presentations, electronic postings and data sharing also contribute to public knowledge, but do not substitute for peer-reviewed publications.

BMT CTN will comply with NIH public access policies including submission of study results and final manuscripts (e.g., clinicaltrials.gov, PubMed central, etc.). The BMT CTN will comply with all journal requirements (e.g., modified copyright transfer agreements, disclaimers, etc.) as consistent with NIH policy.

Types of BMT CTN papers include, but are not limited to:

- Primary report of data
- Report of protocol-defined ancillary studies
- Report of protocol-independent analyses from one or more studies
- Report of secondary analyses/Report of technical or administrative committee issues or analyses
- Presentations or abstracts

8.1.1. Oral Presentations Related to BMT CTN Studies

Oral presentations to local groups, which are limited to the design or rationale of the BMT CTN sponsored protocols, are exempt from the review policy described below. Material will not be recorded, published, or re-presented without Publications Committee approval.

8.1.2. Press Release Requirements

Press releases relating to any BMT CTN-led study activity, including but not limited to study activation, first patient enrollment, and study results, must be approved by the BMT CTN DCC leadership team (MCW, NMDP and Emmes Principal Investigators or their designees) and NIH. The approval process may take up to ten business days. The DCC will provide "About The BMT CTN" boilerplate language which must be included in the press release.

8.2. The Role of the Publications Committee

The Publications Committee is responsible for developing publication and presentation policies. All policies must be approved by the Steering Committee before implementation.

The Publications Committee reviews all proposed publications and presentations to assess scientific rigor and relevance to the BMT CTN mission. This review process ensures protection of proprietary information and study participant confidentiality and assesses the public impact of publication and/or presentation.

No participating institution, BMT CTN Technical Committee, Protocol Team or other individual may present or publish individual findings from work performed on study protocols or work related to BMT CTN meetings and conference calls without review of the Publications Committee,

NHLBI and NCI. This includes methodologic or position papers related to BMT CTN protocol development or operations.

8.2.1. Membership

Members are identified from a slate of candidates put forth by the Nominating Committee. The Steering Committee approves these selected individuals. At least one member should represent an Affiliate Center.

8.2.2. Amendments to Publication/Presentation Committee Guidelines

Changes to the review policies will be subject to review, amendment and approval by the Steering Committee.

8.2.3. Conflict of Interest

In the event a member of the BMT CTN Publications Committee is asked to review a manuscript, publication or presentation in which he/she is listed as an author, they should recuse him/herself from adjudicating the document.

If both the BMT CTN Publications Committee Chairs are included in the author list, they will take responsibility for re-assigning an Interim-Chair to review the manuscript, publication or presentation.

If more than three members of the Publications Committee are included in the author list, the Publications Committee Chairs will be responsible for assigning ad-hoc reviewers to review the manuscript, publication or presentation.

8.3. Review Timeline

Abstracts, presentations, and proposed publications relating to data obtained from BMT CTN protocols or to activities of BMT CTN Committees or Protocol Teams are to be submitted to the DCC Publications Committee Liaison. The Liaison will distribute abstracts, presentations and proposed publications to the Publications Committee for review. The Committee will have five (5) business days to make recommendations to the Corresponding Author concerning abstracts and presentations and ten (10) business days to make recommendations to the Corresponding Author concerning publications. If an expedited review is necessary, the Chairs may determine their review will suffice.

If Publication Committee members have concerns about the submitted materials and/or appropriateness of data, the Committee submits questions and/or recommendations within five days to the Liaison to forward to the Corresponding/Senior Author for resolution. The Committee, at its discretion, may choose to submit questions and/or recommendations to the Steering Committee for resolution if they determine that Steering Committee involvement is required. The Steering Committee is required to provide any responses to the Committee within ten (10) business days.

8.4. Primary Results Manuscript

Manuscripts reporting the results of each BMT CTN trial or BMT CTN methodologic or position papers are prepared and submitted in a timely manner. No clinical trial results are released, presented or published without review from the Publications Committee, NHLBI and NCI.

8.4.1. Data Analysis

The statistical analysis of trial data is performed by the DCC. Final decisions about patient outcomes and endpoints are the responsibility of the protocol team and/or Endpoint Review Committee and are documented in the Statistical Analysis Plan (SAP), if different from the protocol. Upon completion of the statistical analysis, the DCC issues the Data Analysis Report of the study. In general, the Data Analysis Report is available within two months of locking the trial dataset. The Protocol Chair(s) will monitor progress toward completion of the Data Analysis Report. The Protocol Chair(s) may ask the BMT CTN Steering Committee Chair to assist with addressing delays in the completion of the Data Analysis Report.

8.4.2. Writing Responsibilities

Completion of the primary study manuscript is the responsibility of the Protocol Chair(s) or designee(s). The first draft manuscript is completed within three (3) months of receiving the Data Analysis Report and necessary supplemental analyses. Co-authors shall have access to the study Data Analysis Report and shall be afforded ample opportunity to contribute to completion of the manuscript.

If the Protocol Chair(s) or designee is unable to complete the first-draft manuscript in a timely fashion, the DCC has the responsibility to address the delay. If necessary, the DCC Principal Investigator may ask the BMT CTN Steering Committee Chair to re-assign first-draft responsibility to another author who will become the Lead Author on the manuscript.

Upon completion, the Lead Author distributes the first draft manuscript to all co-authors. Author comments are used to generate subsequent drafts and the final manuscript. Authors should settle differences in interpretation by discussion and consensus whenever possible. If consensus cannot be achieved, the decision is made by majority vote. If necessary, the BMT CTN Steering Committee will adjudicate. In general, the time from completion of the first draft manuscript to the final manuscript submission should not exceed four (4) months.

8.4.3. Timelines

To ensure timely publication of study results, the timelines below should be followed:

- Dataset closure to Data Analysis Report – two (2) months
- Data Analysis Report to first draft manuscript – three (3) months
- First draft manuscript to submission –four (4) months

8.5. Secondary Manuscripts

Manuscripts arising from the study outside the primary trial endpoints are considered secondary manuscripts. These include:

- Reports of analyses of secondary or exploratory endpoints pre-specified in a protocol
- Reports of ancillary or correlative studies defined in the primary trial protocol
- Secondary analyses of one or more BMT CTN trials
- Independent ancillary studies not pre-specified in the primary trial protocol
- Methodological papers
- Position papers
- Other technical reports

For secondary analyses included in the protocol, the protocol team should develop a publication plan and establish authors for each paper using authorship guidelines below. All manuscripts must follow the same review process as a primary results manuscript as detailed in Section 8.4.

8.6. Manuscript Requirements

All manuscripts of the BMT CTN are subject to the following requirements:

- Titles
  - The manuscript title should include the words "Blood and Marrow Transplant Clinical Trials Network," if permitted by the Journal.
  - If not permitted in the title, manuscript text should include language such as "…. submitted on behalf of the Blood and Marrow Transplant Clinical Trials Network (BMT CTN)." The Methods section is the preferred section for this reference.
- Acknowledgments
  - General
    Other investigators not part of the authorship list but who have made significant contribution to the conduct of the study, as well as staff members from a Clinical Center, DCC or NIH, are noted. Each primary study manuscript must include a listing of all participating clinical centers and the responsible study physician at that center.
  - Government Sponsors
    Each manuscript must acknowledge all NIH funding sources for the study, including in every instance, funding from NHLBI and NCI to the DCC and the participating Clinical Centers using the following language: "The Blood and Marrow Transplant Clinical Trials Network is supported in part by grant #U10HL069294 and U24HL138660 from the National Heart, Lung, and Blood Institute and the National Cancer Institute."
  - Other Networks/Cooperative Group involvement
    - Manuscripts for BMT CTN-led studies involving collaboration with other Networks or Groups must acknowledge the Network/Group as specified by the Primary Network/Group Investigator and Publications Committee Contact involved with the study.
    - Manuscripts for studies endorsed by the BMT CTN but led by other Networks or Groups must acknowledge the BMT CTN appropriately. The DCC Business Representative will inform the Primary Network/Group Representative and Investigator of the procedure for publication review and acknowledgments. A final draft of the manuscript must be submitted to the BMT CTN Lead Author (see

below) and DCC Business Representative before submission to ensure appropriate acknowledgement is made.

- Non-government Support
  The Contributors must be acknowledged in concordance with the active Memorandum of Agreement (MOA). Generally, contributors are provided a draft copy of all publications and allowed at least thirty (30) days to review the information and provide comments as detailed in the MOA.

- The DCC Business Representative reviews materials in advance to confirm that contributors are accurately acknowledged
- Protocol-specific and Cooperative Group Publication Instructions are located on the BMT CTN public website: https://bmtctn.net/author-resources.

8.6.1. Approvals and Submission

- The First or Last Author are responsible for submission of the final manuscript and for obtaining written approvals from all authors as well as the representatives of the DCC, NHLBI and NCI. The DCC requires that First/Corresponding Authors complete internal abstract and manuscript review checklists for this purpose prior to submission of materials to assure that all required approvals are obtained and that contributors and/or sponsors are acknowledged accurately. These checklists are available on the BMT CTN public website: https://bmtctn.net/author-resources. In addition, the BMT CTN Lead or Corresponding Author will conduct final review of the manuscript to ensure accurate and complete acknowledgments. They will also keep co-authors informed of any revisions, replies to reviewer feedback, and re-submissions. For BMT CTN studies, the BMT CTN Lead Author is the First Author; for cooperative group led studies, the BMT CTN Lead Author will be assigned and may not be the First Author.

  The Lead Author is responsible for obtaining approval from all co-authors. In addition, the Lead Author should send all submission materials to the DCC for circulation to the following people 30 days prior to the planned manuscript submission (7 days for presentations/abstracts):

  - DCC co-PIs
  - Publications Committee
  - DCC Business Representative
  - NHLBI/NCI Program Officers
  - Primary Network/Cooperative Group and Publications Committee Contact representative, if applicable
  - Contributors, if applicable

- The Corresponding Author should ensure that each author and the DCC, NHLBI and NCI representatives receives a final copy of the submitted manuscript, abstract or presentation.

Review, correction and return of galley proofs are the joint responsibility of the Lead and Senior Authors and the Protocol Statistician. For collaborative studies led by the BMT CTN, the Primary Network/ NCTN Group and Publications Committee Contact representative should also review the galley proofs. For NCTN Group led studies, the BMT CTN Lead Author will provide BMT CTN acknowledgment requirements to the First Author and review the final manuscript proof, or

any deviations from the BMT CTN acknowledgment requirements, prior to manuscript submission. The final manuscript proof must also be provided to the DCC leadership team.

8.7. Authorship Guidelines

Authorship guidelines are based on fairness, inclusion and degrees of participation and compliance. Authorship recognizes a consistent focus on intellectual input and effort extended during the lifecycle of the trial. The Publications Committee is responsible for the development and modification of guidelines for determining authorship. Authorship guidelines are ratified by the Steering Committee prior to implementation.

Authorship on BMT CTN publications is a privilege commensurate with both personal and center contribution to the research being presented and the Network as a whole. The primary requirement for authorship of a BMT CTN publication is a substantive contribution to the research effort and is a recognition for many aspects of contribution including: (1) membership and active participation in the Protocol Team; (2) active accrual to the protocol; (3) timely and accurate reporting of data; and, (4) active participation in relevant Steering Committee activities. These activities may include participation in the following areas: hypothesis generation, concept development, protocol development, study implementation, subject enrollment, data collection, data analysis, and manuscript preparation and finalization. In most instances, contributions in several areas must occur, and in every instance, authors are expected to contribute to manuscript preparation and finalization.

The fundamental premise of authorship designation is the recognition of overall effort. First and senior authorship positions on manuscripts should be broadly shared among Protocol Team members. First and senior authorship on the primary paper does not imply the same position on any subsequent manuscripts resulting from the same completed protocol or related ancillary studies.

8.7.1. Authorship Eligibility Requirements

Each member of the Protocol Team has eligibility for authorship on the final primary manuscript from the study. In addition, each Clinical Center Principal Investigator whose center enrolls at least one subject in the study is eligible for authorship. Additional authors may be invited at the discretion of the Protocol Chair(s), in consultation with the Protocol Team, with approval of the Publications Committee Chairs or full Committee, if needed. Eligibility for authorship does not guarantee authorship. Eligible authors must still make substantive contributions, including careful review and contributions to the draft manuscript.

8.7.2. Establishing the Order of Authorship for Primary Results Manuscript

For each manuscript, the Protocol Chair(s) and Protocol Officer will recommend the co-authors and the order of authorship based on the Administrative MOP parameters. Any potential additional authors proposed outside the scope of the Administrative MOP should be reviewed and approved by the Publications Committee with documented reasoning. The Protocol Officer will also assess Protocol Chair authorship order based on accrual and participation metrics posted on the public website and get approval/adjudication from the Executive or Publications Committee if needed. If there are multiple Protocol Chairs, two Chairs may share first or last authorship, provided they meet the below requirements and the journal allows this practice. Authorship order may differ for

manuscripts and abstracts. The Publications Committee will adjudicate any disputes, approve any requests for exceptions for special circumstances, and may also recommend additional authors after review of accrual tables and based on justifiable, well-documented reasoning.

Approved requirements for author order are as follows.

- SENIOR (last) AUTHOR REQUIREMENTS
    - Protocol Co-Chair [for primary results manuscripts]
    - Attended majority of Protocol Team Calls
    - Author's center actively participated in the trial
    - Author's center showed commendable protocol compliance and data submission
- FIRST AUTHOR REQUIREMENTS
    - Same as above Writes the first draft of the manuscript
- AUTHORSHIP BASED ON PROTOCOL TEAM AND ENDPOINT REVIEW COMMITTEE (ERC) PARTICIPATION
    - The second and third authors should be the Protocol Officer or Primary DCC PhD Statistician. In special circumstances protocol team/ERC members may be selected as second and/or third authors for exceptional contributions (other than accrual). The order will be determined by the Protocol Chairs and will be reviewed and approved by the Publications Committee.
    - Each Protocol Team/ERC member will be an author, in order of accrual, if the following criteria are met:
        - Attended the majority of Protocol Team/ERC calls
        - Author's center actively participated in the trial
        - Author's center had satisfactory protocol compliance and data submission
    - If a center has more than one member represented on the Protocol Team/ERC, only one member is eligible to be an author under this criterion. The other Protocol Team member(s) may be eligible for authorship if they meet any of the additional authorship criteria.
- AUTHORSHIP BASED ON CENTER PARTICIPATION IN ORDER OF ACCRUAL
    - The top ten accruing centers will have a single author in order of accrual, and with meaningful contributions, the top two accruing Affiliate Centers. If the study involves international centers, the top five U.S. and top five international centers will each have a single author. In addition, if there are U.S. centers with significantly greater accrual than the highest accruing international centers, up to three U.S. centers will have an author included. If not included in this list, a single author from the center with the highest accrual from groups underrepresented in medicine will be invited.
    - If the First or Last Author is from one of these centers, a Second Author from that center may be added
    - Author identity should generally be the site PI, unless that person is an author based on other criteria, in which case the identify is determined by center PI
    - Author's center must have also had satisfactory protocol compliance and data submission

- BMT CTN PUBLICATIONS LIST ALL CENTERS THAT PARTICIPATED
    - Any center that has enrolled at least one patient will be acknowledged in the publication
- CONSIDERATIONS FOR ADDITIONAL AUTHORS
    - A physician can be named in acknowledgement of overall effort, exceptional accrual and/or supportive input throughout the lifecycle of the study
    - An additional author from a same center mentioned above can be named if he/she has shown exceptional accrual or intellectual input. These can be non-physicians, e.g.:
        - Nurses and advanced practice providers
        - Study coordinators
        - Pharmacists
- SPECIAL CONSIDERATIONS FOR TRIALS OF RARE DISEASES

  The BMT CTN acknowledges that some indications for transplantation are sufficiently rare that many centers must be activated, with the likelihood that some will not accrue any or many patients. Possibility of authorship is a good incentive for participation in trials that may be difficult to open and hard to maintain. In trials designated by the Executive Committee as Rare Disease trials, the PI at each center that activates the study is eligible for authorship if they provide input to data review, analysis and/or manuscript preparation.
- IF THE JOURNAL OR ABSTRACT GUIDELINES LIMIT THE NUMBER OF AUTHORS, AUTHORS WILL BE DELETED IN THE FOLLOWING ORDER:
    - Remove Protocol Team members and top accruing centers in reverse order of center accrual
    - Remove Secondary Statistician
    - Minimum author assignments will be First, Last, Protocol Officer and Primary Statistician

8.7.3. Establishing the Order of Authorship for Secondary Results or Ancillary Study Manuscripts

Secondary results manuscripts will follow similar authorship guidelines as described for primary results manuscripts. However, special recognition is given to those who were not considered for First and Senior Authors on the primary paper. Consideration as added co-authors is extended to other Protocol Team members such as DCC members, clinical research coordinators and Early-Stage Protocol Team members, especially those from centers with good accrual rates.

Protocol Chairs and Officers will assign, as soon as is feasible, writing committees for secondary results manuscripts. They should offer the opportunity to lead these analyses to site PIs, with a focus on early and mid-career investigators. Proposals for secondary results manuscripts will be reviewed by the Protocol Team and authorship appropriately assigned.

For secondary analyses or ancillary studies conducted outside the purview of a Protocol Team that is actively still meeting, the protocol team should be invited to participate and given the opportunity to be co-authors on the manuscript. For secondary analyses or ancillary studies conducted outside the purview of a Protocol Team that is no longer actively meeting, the Protocol

Chairs of the parent study should be invited to participate and given the opportunity to be co-authors on the manuscript for studies that are conducted within five years of publication of the primary results manuscript. In either case, authorship consideration should also be given to investigators from the highest accruing centers and/or centers that provided a significant proportion of biospecimens, if applicable. An exception to this policy is if the ancillary study uses biorepository specimens and/or clinical data from multiple studies and the analysis is not related to the parent study's specific design.

8.7.4. Removing Authors

An author may not be invited or may be removed from the final manuscript upon failure to make substantive contributions to the overall project. The Lead Author may request that another author withdraw from authorship. The Publications Committee Chairs, or at the Chairs' discretion, the Publications Committee shall adjudicate authorship disputes by simple majority rule. If an author is removed, another eligible author may be added.

8.7.5. Authorship on Joint Studies

These studies primarily involve the NCI NCTN Groups. The BMT CTN Steering Committee supports the approach that the two study chairs representing the collaborating groups hold the first and last author positions at the time of manuscript preparation; this should be decided in advance by the Protocol Team.

8.8. Abstracts, Public Presentations, Electronic Postings

8.8.1. General

Abstracts, public presentations of study data and electronic postings of study data generally follow the same processes outlined for primary publications as noted above but may not include all authors included in the final manuscript.

8.8.2. Abstracts

Abstracts focusing on study results should only be submitted to one meeting unless there are additional results to present or another cogent reason to re-present the results. If submitting the same abstract to a subsequent meeting, the authors must provide justification to the Publications Committee and BMT CTN DCC leadership. An exception is Trials in Progress abstracts, which may be submitted to multiple meetings.

All abstract authors must have made substantive contributions to the study. Acknowledgments of funding sources are not required in the abstract text but must be included in the presentation slides or poster materials, if the abstract is accepted. The BMT CTN PowerPoint or poster template must be used when presenting oral or poster abstracts of BMT CTN-led studies.

The first or last author is responsible for submitting the abstract. Proposals for abstract submissions should be initiated well in advance of the abstract submission deadline. The Publications

Committee prioritizes their review process in the following way: peer-reviewed publications receive higher priority than abstracts, public presentations, and electronic postings.

8.8.3. Public Presentations and Electronic Postings of Study Data

In general, a complete set of summary slides is prepared by the Lead and Senior Author and Protocol Statistician upon completion and analysis of each BMT CTN study. Individual investigators who wish to prepare additional slides for public presentation must utilize data from the final Data Analysis Report. Such presentations must also be submitted to the DCC for submission to the Publications Committee Chairs, their designee, or at the Chairs' discretion, the entire Committee, for review and approval. Each such presentation must also acknowledge the authors, funding agencies, contributors and the participating Core and Affiliate Centers. Electronic posting of study data must not occur prior to publication of the study's primary manuscript in a peer-reviewed journal.