Date: February 3, 2023

NCI/DCTD Co-Authorship Guidelines for Overarching Publications of NCI-NCTN Group Collaborative Precision Medicine Initiatives

The following guidelines are developed to recognize the specific and intensive effort undertaken by both the National Cancer Institute (NCI)-funded National Clinical Trials Network (NCTN) Groups and the NCI in developing and managing the large and complex Precision Medicine trials. The purpose of this document is to set down expectations for authorship that have been agreed between Dr. James H. Doroshow, representing the NCI Division of Cancer Treatment and Diagnosis (DCTD), and the NCTN Group Chairs and their respective Publication Committees via the contact principal investigators for the NCTN Group Operations Center grants as listed at the end of this document. The following principals should be applied:

1) Co-authorship positions should be based on the principle of equitable sharing between NCI and the lead NCTN Group.
2) The leadership of the NCI/DCTD and each of the involved NCTN Groups are responsible for determining which individuals should be considered for co-authorship based on the stringent application of their respective internal SOPs for co-authorship.
3) The authorship discussion should be initiated during protocol development stage and approved potential co-authors, including the Principal Investigator/Study Chair, Disease Site Chair (if applicable), Biostatistician, Disease Site Co-Investigators, and Study Champions (if applicable) should appear on the approved Master Protocol Face Sheet; it is recognized that final decisions as to the priority of contributions will need to be made at the time of analysis for individual trials/studies.

Purpose

The intent of this document is to ensure recognition of the substantial contributions by relevant NCI investigators as defined below, including those serving as Co-Principal

Investigators, if applicable. It is expected that the most important positions (first, second, third, penultimate, and last) will be filled by the co-principal investigators from NCI and the NCTN Groups, including statisticians, molecular diagnosticians and bioinformaticians, where applicable. Allocation of these slots will be determined recognizing both the key roles of each party in establishing infrastructure for the study, and in the design and management of the study through the years of its accrual. This document addresses these higher profile positions on the publications and the participation of other researchers both within and without the NCI. This document does not address authorship of the individual sub-studies, which will be governed by the policies of the responsible NCTN Group leading the sub-study.

Overarching papers and presentations

It is expected that 1st or co-1st or 2nd authorship will be taken by a key investigator from each of the lead Group and the NCI each to be determined by the Lead Group and the NCI, respectively, and allocated proportional to their level of involvement. Attributions e.g., co-PI, equal effort, co-first author, may be applied among the co-authors as appropriate. Similarly, 3rd and second to last and last authorship will ordinarily be reserved for highly relevant co-investigators with the last 2 positions occupied by a Lead Group and NCI investigator. In keeping with the principle of equitable sharing, the first and last positions should also be shared. The relative positions for each co-author will be established by agreement or by arbitration if needed.

For the manuscript, it is noted that most journals allow multiple "1st" authors with an attribution that they contributed equally to the work. Similarly, last or second to last authorship may be assigned based on overall effort and responsibility (as agreed or arbitrated) and alternating last authorship for significant international meeting podium presentations (ASCO, ESMO, AACR) and for more than a single overarching paper may be considered.

As appropriate, alternating 1st authorship/presentations for significant international meeting podium presentations (ASCO, ESMO, AACR) and for more than a single overarching paper should also be considered.

Laboratory Contributions

Co-authorship for NCI and NCTN Group molecular diagnosticians, statisticians and bioinformaticians providing significant contributions will be made on the author line. If appropriate, inclusion of a "Precision Medicine" Group/Team/Consortium as a single co-author with an accompanying list of the appropriate members who provided effort and meet the definition of authorship as defined by the ICMJE and the Group/NCI, should be provided in a PubMed searchable appendix or supplement.

Arbitration Committee

This Committee will be set up as needed to arbitrate disputes among co-authors that cannot be resolved by discussion. The Committee will be responsible for final decisions relative to co-authorship. It will be comprised of:

- NCTN Group Chairs contact PIs or designees (n = 6)
- DCTD Cancer Therapy Evaluation Program (CTEP), Cancer Diagnosis Program (CDP) and Biometric Research Program (BRP) Associate Directors and designees (n = 6)
- In the event of a tie vote that cannot be reconciled within the Committee, the Committee can select a tie breaker vote from an independent individual to be agreed upon by majority vote of the Committee.

ICMJE Recommendations for Authorship

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- 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.