**CP-CTNet Publication Guidelines**

The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central *upon acceptance for publication*. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication. More information about this policy or the submission process is available on the NIH Public Access Policy website at: http://publicaccess.nih.gov/.

**1.0 CP-CTNet Publication Committee**

The Committee will be composed of representatives from NCI, the LAOs and the DMACC. Questions for the committee should be sent by email to PubsCommittee_CP-CTNet@frontierscience.org.

**2.0 Publications**

The CP-CTNet LAOs and DMACC are responsible for ensuring timely preparation and submission of all publications for peer review. The CP-CTNet LAOs and the DMACC must adhere strictly to the publication policy described below, as written in the Terms and Conditions of Award for each grant.

Acknowledgement of NCI Support and Scope of Publication Policy: Publication or oral presentation of work done via CP-CTNet Cooperative Agreement requires appropriate acknowledgment of NCI support and a disclaimer such as "Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under Award Number xxxxxxx. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." The DCP research team (Program Staff) should be contacted prior to issuing a press release concerning the outcome of this research to allow for coordination. The definition of publications for this Cooperative Agreement includes CP-CTNet abstracts, press releases, print-media articles/manuscripts, electronic media articles/presentations, posters, letters, etc., related to findings and results from NCI-sponsored studies. When appropriate, the relevant NCI Program Staff should also be included as co-authors.

Publication Timelines: Timely publication of CP-CTNet findings is central to the mission of the CP-CTNet and is a primary means by which the CP-CTNet's accomplishments can be evaluated. Timely presentation of a study's findings and results is especially important when a DSMB recommends the public release of this information. Timely presentation of clinical trial findings and results is especially important when related to public policy and clinical practice standards.

It is expected that preliminary results of CP-CTNet clinical trials will be presented at a scientific meeting within 8-12 months of completion of the study analysis (if not sooner based on the relevance of the results). Publication in peer-reviewed literature (not as an abstract) within one year of completion is strongly recommended.

It is also a requirement of these Terms of Award that the results of all CP-CTNet studies be submitted as required by the Food and Drug Administration Amendments Act (FDAAA) Section 801 to comply with the rules defined for inclusion of clinical trial information in clinicaltrials.gov.

Pre-Publication Review:

- For publications associated with NCI-sponsored CP-CTNet studies, all manuscripts should be submitted to the NCI, DCP PIO for official review. The CP-CTNet Director, Medical Monitor, Scientific Lead, and Nurse Consultant should receive a copy of the manuscript 30 days in advance of submission and a draft of an abstract no later than 3 days (but preferably at least 7 days) in advance of submission. Review timing for publications other than abstracts or manuscripts should be discussed with appropriate DCP Program Staff.
- All press releases issued by the NCI and/or the LAO or AO or DMACC on primary study findings and results require review by NCI. Pre-review timing for press releases on study finding and results must be discussed with and approved by the CP-CTNet Director, Medical Monitor, Scientific Lead, and Nurse Consultant for all cancer prevention clinical trials. The LAOs and DMACC are encouraged to send drafts of press releases on other topics to NCI Program Staff (Medical Monitor, Scientific Lead, and Nurse Consultant) for pre-review and/or pre-release notice.
- In addition to the requirements listed above, LAOs and DMACC should consider carefully whether any findings from clinical trials that are pending reporting/publication may have major impact for public health or public policy. If there is the potential for major impact for public health or public policy, the LAO or DMACC must inform the CP-CTNet Director, Medical and Scientific Lead and work closely with NCI to ensure that the information is released to the public in as timely a manner as possible and in a manner to ensure appropriate communication about the results, including how they may affect other ongoing trials and the treatment of participants on those trials, public policy or current clinical practice.

**3.0 Authorship Criteria**

CP-CTNet adheres to the ICMJE authorship guidelines, which are based on the following 4 criteria:

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. Additional details can be found at www.icmje.org

Authorship discussion should be held during protocol development stage, although author contributions may evolve over time and additional authors may be added subsequently (e.g., for biomarker work). The leadership of each group (NCI, CP-CTNet LAO, DMACC) involved in the study is responsible for determining which individuals should be considered for co-authorship.

- The Protocol Principal Investigator (PI) makes final decisions about who is listed on the manuscript, and the order
- If a journal imposes limits on the number of authors, the Protocol PI makes final decisions

**Primary Manuscript/Presentation**

- The Protocol PI decides on the first author, often the junior person heavily involved in the trial conduct/analysis and writing.
- Other key contributors follow, as determined by the Protocol PI based on the extent of involvement of each investigator in the work.
- Site PIs follow in the order of site participant accrual.
- NCI personnel should be included as appropriate.
- The network PI is generally the second-last (or last if the Protocol PI is the first author).
- The Protocol PI is usually either the first or the last and corresponding author; may choose to share corresponding designation with other key contributors.
- For studies arising from concepts solicited by NCI Staff, the responsible NCI Scientific Program Staff (e.g., Scientific Lead or Medical Monitor) should share senior authorship with the Protocol PI. If the Protocol PI is not first, then he/she should be last and the DCP Program Staff should be second-last.
- As appropriate, the following LAO/AO/DMACC Study Team members should be included: statistician, site coordinators or other personnel who have an important impact on accrual, lab personnel who perform biomarker analyses, pathologists, radiologists, anyone critical to the conduct of the study who meets the definition of authorship as defined by the ICMJE

**Acknowledgments**

- DMACC should be acknowledged for its coordinating and support functions (U24CA242637).
- The contributions of DCP's contractors who supply regulatory and agent repository services (e.g., CCS Associates, Inc; MRI Global) should be acknowledged as appropriate.
- Specific personnel from these contractors or from the AO, LAO, or DMACC who provided extraordinary contributions but do not merit authorship may be mentioned by name.
- Study participants should also be thanked.

**Secondary Manuscripts/Study Analysis**

The Protocol PI will determine the authorship for Secondary Manuscripts/Study Analyses. Individuals who wish to conduct planned or previously unplanned secondary analysis should contact the Protocol PI.

- Authorship on these manuscripts should include, as appropriate, individual members who provided input and meet the definition of authorship as defined by the ICMJE:
    - Protocol PI
    - LAO/DMACC PI
    - Staff responsible for Secondary and Biomarker Analyses
    - Biostatistician
    - Other contributing authors

**Abstracts**

Principles similar to the above should be used to determine authorship, authorship order, and abstract presenter. Abstracts must be submitted to the LAO and to the NCI, DCP PIO for formal review as discussed in the section on "Pre-Publication Review".

**4.0 Dispute resolution**

- CP-CTNet PIs should resolve authorship disputes for studies within their own LAO or DMACC.
- The Publication Working Group should be consulted to resolve authorship issues within an LAO or for cross-network trials