Manual of Procedures (MOP)
Section 2. Policies and Procedures
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1 OVERVIEW & DEFINITIONS

1.1 Overview

The purpose of this document is to set forth the guidelines by which D2d study data and procedures will be shared with the scientific community.

1.2 Definitions

- **Study Group:** The group of D2d investigators that are considered key personnel according to NIH criteria.
- **Research Group**. The group of personnel who are employed at any D2d component (e.g. CC, collaborating clinical site) and contribute a portion of their effort to the D2d project with funding from the U01 grant.
- **Collaborator:** Any investigator who is not a member of the Study Group but who participates in research conducted under the auspices of D2d with independent funding or through donation of effort. For example, investigators of ancillary studies are considered collaborators.
- **Consultant:** Any professional who provides service of limited nature (e.g. fee-based or *pro bono*) to D2d.
- **Ancillary Study:** An investigator-initiated research activity that is not part of the core D2d study protocol (e.g. has not been previously described in the D2d study protocol; entails new measurements or evaluations of D2d participants). Such studies will require approval by the Ancillary Studies Subcommittee (ASS), the Steering Committee (SC) and DSMB prior to implementation. The ancillary study investigators would be considered collaborators per above. The publications or presentations of the research proposed in the ancillary study would comply with the policies stated herein.
- **Core analyses**. These are proposals for manuscripts that are developed at the start of the D2d study and are based on the protocol (e.g. trial design, baseline characteristics, primary outcome, pre-defined secondary outcomes).
- **Ancillary Analysis.** An analysis of existing D2d study data that addresses questions not addressed by the planned core analyses. Ancillary analyses are different from ancillary studies because they do not require additional measurements or evaluations of D2d participants. Ancillary analyses require approval by the Publications and Presentation Subcommittee (PPS) and SC. The publications or presentations of the ancillary research would comply with the policies stated herein.
- **Publicly Independent Research:** D2d data and biological specimens will be made available to investigators in the scientific community through the NIDDK Central Repository. The D2d study will play no role in the conduct of such research or in the publication or presentation of such research, and the policies herein would not apply. However, D2d requests that all publications and presentations using materials that originated with D2d provide an appropriate acknowledgement.
- **Press Release:** A statement released to print, non-print or electronic media that is not scientifically indexed.
- **Interview:** Any communication with a print, non-print or electronic media reporter, who in turn provides information for public dissemination.
- **Presentation:** The formal delivery of information to scientific, professional, or public groups.

- **Publication**: Any document submitted to a professional journal indexed scientifically, any lay publication, or a document that would appear as part of a book in whole or in part. A book is any material that has been assigned an International Standard Book Number (ISBN) or an electronic document that has been assigned a Digital Object Identifier (DOI).
- **Writing Group.** Two or more persons working together to produce a communication document (e.g. abstract, publication, presentation) that uses D2d data. Writing group may be proposed by the individual members of the group or by a study committee (e.g. EC, PPS). All writing groups need to be approved by PPS.

2 SCOPE OF THE POLICY

- This policy applies to anyone, within the D2d Research Group or outside collaborators (including ancillary studies), proposing analyses, presentation(s), or publication(s) that uses D2d study data.
- This policy applies to full manuscripts (including methodology and validation papers), letters to the editor, abstracts/extended abstracts, oral and poster presentations that use D2d study data, including data collected as part of an ancillary study.
- This policy applies to press releases and interviews that reference the D2d study.
- This policy remains in force until the data are submitted to the NIDDK Central Repository. At that time, the data sharing and publications policy of the Repository will go into effect.

3 PUBLICATIONS & PRESENTATIONS SUBCOMMITTEE (PPS)

All analyses, publications and presentations generated using data from the D2d study will be under the auspices of PPS.

The objectives of the PPS are to:

- Encourage the development of high-quality peer-reviewed scientific manuscripts and presentations with broad participation by the D2d Research Group.
- Encourage the development of collaborations with investigators outside of the D2d Research Group who will conduct additional research to augment the core research goals and maximize the return on efforts in the D2d study.
- Preserve the scientific integrity of the D2d study in publications and presentations.
- Protect the rights and privacy of study participants in publications and presentations.

The duties and responsibilities of the PPS are provided in detail in the PPS Charter (see MOO Section 1, Appendix 1.6).

4 OFFICIAL COMMUNICATIONS (PUBLICATIONS, PRESENTATIONS ETC.)

The PPS will review and approve all official communications, including publications and presentations related to the D2d study, prior to submission and will work with the authors to monitor the progress of all proposals to ensure prompt completion and publication. The PPS will also review and approve press releases and interviews.

⇒ All communications with the PPS will be via the Coordinating Center (CC) via the email: d2d@tuftsmedicalcenter.org.

All proposals for communications (publications etc.) should come from within the D2d Research Group or from an approved ancillary study investigator. Proposals may be submitted by individuals or from a group of investigators (i.e. writing group).

All authors are expected to fully comply with the conflict of interest uniform reporting forms as provided by New England Journal of Medicine and more than 100 other journals. Any potential conflict of interests relative to industry support must be provided to the PPS at the time the communication material is submitted for review by the PPS.

4.1 Proposals and Manuscripts

4.1.1 Proposals for manuscripts

- Proposals for manuscripts for ancillary analyses should be submitted to PPS (d2d@tuftsmedicalcenter.org) by the lead author, on behalf of the writing group, before any data analysis takes place. The lead author will designate whether the proposal is considered Tier 1, 2 or 3 (see below).
- A proposal is not required if the manuscript has been previously approved as part of an ancillary study.
- Proposals will be indexed as “PRYY-NN,” where “PR” stands for proposal, “YY” is the year of submission to the PPS and “NN” is a serial number specified by the CC.
- The EC, SC or PPS may also designate a topic and identify the lead author and writing group.
- Investigators outside of the D2d Research Group (e.g. research fellow at the CC or at a site) may serve as lead author on a proposal, provided at least one D2d investigator serves as a co-author and "sponsor" of the project.
- Addendum manuscript proposals may be submitted for an additional manuscript relating to a previously approved manuscript proposal (e.g. P13-02A, P13-02B as an addendum to P13-02), or ancillary study (e.g. AS12-01A as an addendum to AS12-01) if the work is closely related. The first author of the original manuscript proposal should be included in the addendum manuscript proposal.
- Proposals will be submitted using the proposal submission form.
- During review, the PPS will ensure that:
  - There are no conflicts with any other proposals.
  - The proposal would not interfere with the study (if ongoing).
  - Methodology description and proposed data analyses are appropriate and consistent with other D2d publications.
- The PPS will respond within 4 weeks. Members of the PPS will be given 3 weeks to review the submitted material and convey their comments as a committee. It is expected that all PPS members will review all submissions. PPS members who do not submit any comments within the allotted time will be assumed to approve the submission as is.
- Depending on the Tier designation (see below), the proposal may also need to be reviewed and approved by the SC.

- Approval of the proposal, suggested modifications or rejection of the proposal will be communicated to the lead author. The PPS may also recommend additional contributors to the writing group to serve as co-authors.
- It is expected that all abstracts, manuscripts and presentations will be derived from an approved proposal.

4.1.2 Manuscripts

- Manuscripts will be considered by the PPS only for topics/analyses (i.e. proposals) that have already been approved by PPS (or ASS) and used data that have been officially released by the CC.
- Requests for additional data from the CC, that may be required to enhance the scientific rigor of the manuscript, need to be approved by PPS or, if the manuscript involves an ancillary study, by ASS.
- Manuscripts must be reviewed and approved by all co-authors (i.e. writing group) prior to submission to the PPS for review and approval. Submission of a manuscript by the lead author assumes that all co-authors have contributed to the abstract and have approved the submitted version.
- The lead author must submit the manuscript to the PPS (d2d@tuftsmedicalcenter.org) and will designate whether the abstract is considered Tier 1, 2 or 3 (see below).
- During review, the PPS will ensure that:
  - Manuscripts are consistent with the proposal previously approved, and do not overlap with existing manuscripts (in preparation or published).
  - Methodology description, data analyses and interpretation are appropriate and consistent with other D2d publications.
- The PPS will respond within 4 weeks. Members of the PPS will be given 3 weeks to review the submitted material and convey their comments as a committee. It is expected that all PPS members will review all submissions. PPS members who do not submit any comments within the allotted time will be assumed to approve the submission as is.
- Depending on the Tier designation (see below), the manuscript may also need to be reviewed and approved by the SC.
- Approval of the manuscript, request for revision, or rejection of the manuscript will be communicated to the lead author. The PPS may recommend additional co-authors and/or an appropriate journal.
- If revisions are requested, the lead author must submit a revised manuscript to PPS for review.
- Following communication of acceptance by PPS, the lead author may submit the manuscript for external peer-review.
- If the manuscript requires minor revisions or is not accepted, the lead author can proceed with submitting a revised version or to another journal provided no major modifications to the data analyses/interpretation have been made. If major revisions are requested by the journal, the revised manuscript will need to be reviewed/approved by the PPS before re-submitting.
- The lead author must submit to the PPS (d2d@tuftsmedicalcenter.org) an e-copy of the final accepted manuscript and its citation.

2.4.2 Abstracts and Presentations

4.2.1 Abstracts

- Abstracts to scientific meetings will be considered only for topics/analyses (i.e. proposals) that have already been approved by PPS (or ASS) and have used data that have been officially released by the CC.
- Requests for additional data from the CC must be must be made at least 12 weeks prior to abstract submission. These requests need to be approved by PPS or, if the abstract involves an ancillary study, by ASS.
- Abstracts must be reviewed and approved by all co-authors (i.e. writing group) prior to submission to the PPS for review and approval. Submission of an abstract by the lead author assumes that all co-authors have contributed to the abstract and have approved the submitted version.
- The lead author must submit the abstract to the PPS (d2d@tuftsmedicalcenter.org) at least 4 weeks prior to the submission deadline for the upcoming scientific meeting. The lead author will designate whether the abstract is considered Tier 1, 2 or 3 (see below).
- The PPS will respond within 2 weeks. Members of the PPS will be given 10 days to review the submitted material and convey their comments as a committee. It is expected that all PPS members will review all submissions. PPS members who do not submit any comments within the allotted time will be assumed to approve the submission as is.
- Depending on the Tier designation (see below), the abstract may also need to be reviewed and approved by the SC.
- During review, the PPS will ensure that:
  - Abstracts are consistent with the proposal previously approved, and do not overlap with existing abstracts or manuscripts (in preparation or published).
  - Methodology description, data analyses and interpretation are appropriate and consistent with other D2d publications.
- Approval of the abstract, request for revision, or rejection will be communicated to the lead author. The PPS may recommend additional co-authors.
- If revisions are requested, the lead author must submit a revised abstract to the PPS for review.
- Following communication of acceptance by the PPS, the lead author may submit the abstract.
- The lead author must submit to PPS (d2d@tuftsmedicalcenter.org) an e-copy of the final abstract, notification of acceptance and, if published, its citation.
- Abstracts submitted to scientific meetings without PPS approval must be withdrawn. Failure to withdraw may result in sanctions that may jeopardize current and future approval decisions.

4.2.2 Presentations

- After an abstract is accepted for presentation to a scientific meeting, the presentation (poster or oral presentation) also needs to be reviewed and approved by PPS. The same procedure as with abstracts will be followed (e.g. the presentation slides or poster must be reviewed and approved by the writing group prior to the presentation; the lead author must submit the presentation to the PPS at least 2 weeks in advance and will designate the presentation as Tier 1, 2 or 3; the PPS will respond within 1 week etc.).

- The CC has a template (i.e. standard style) to be employed for all D2d-related slide presentations and posters. It is the responsibility of the lead author to obtain an e-copy of the slide or poster template by the CC.
- It is expected that posters/oral presentations will be derived from abstracts that have received prior PPS approval. If there is no prior approval, the review process for presentations will be handled in the same manner as for abstracts.

⇒ *Invited Presentations*: If individual members of the D2d Research Group are invited to present D2d-related data or to represent the D2d Research Group, then the invitation must be forwarded to the CC that will manage all such invitations on behalf of the Research Group.

4.3 Press releases and Interviews

It is crucial that certain procedures are followed to ensure uniformity and accuracy in the information disseminated through the media.

4.3.1 Press releases

Press releases related to the overall conduct or major results of D2d will be issued centrally by the funding agency (NIDDK). All such press releases will then be distributed to all study components for simultaneous release by their local press offices timed to the release centrally. These prepared releases should be provided to the media when interviews are requested.

There should be no press release related to study results that have not been published or presented at a scientific meeting or previously approved by PPS.

Individual sites can issue press releases related to the site activities in D2d (e.g. to promote recruitment) provided that the release is limited to information available in the most recent version of the Protocol or in manuscripts already published. There should be no added interpretations or inferences. Such releases do not require prior review and approval by PPS. The CC will provide sites with samples of press releases that they can modify according to local needs.

4.3.2 Interviews

A D2d Research Group member can provide a statement or interview without prior review and approval by PPS, provided that the release is limited to information available in the most recent version of the Protocol or in manuscripts already published. There should be no added interpretations or inferences.

⇒ If individual members of the D2d Research Group are invited for an interview to discuss the overall conduct or major results of the study, then the invitation must be forwarded to the CC that will manage all such invitations on behalf of the Study Group.

4.4 Acknowledgment of Funding

The study's support must be acknowledged on all reports, publications, press releases, etc. The CC will provide a statement acknowledging the sponsors of the D2d study that has been approved by the

Executive Committee (see Appendix). If the paper or presentation emanates from an ancillary study, initiative or supplemental analysis supported by independent funding, the sponsors of the research should also be cited, in addition to the standard D2d sponsor acknowledgment.

5 CATEGORIES OF PUBLICATIONS

The following categories apply to publications and presentations (including abstracts) generated on behalf of the D2d Research Group, including ancillary analyses and ancillary studies. The lead author will recommend tier designation but the final responsibility for the tier assignment for each manuscript will rest with PPS and EC, usually at the time that the proposal/manuscript is approved. Please see section on Authorship Guidelines for how to report authorship.

- Tier 1, Primary D2d outcomes: These are protocol-specific publications that report the main outcomes of the study or any other major finding from D2d that, in the opinion of PPS and SC, merit a tier 1 designation. Proposals for tier 1 publications generally emanate from the EC. Examples of tier 1 publications include: trial design; baseline characteristics; overall safety and effects of vitamin D supplementation on the primary outcome.
  ⇒ Both PPS and SC must approve all Tier 1 publications before submission for external review.

- Tier 2, Secondary D2d outcomes: These publications includes analyses of secondary outcomes, ancillary analyses (which are not part of ancillary studies) or epidemiologic analyses emanating from the core D2d study that do not merit a tier 1 classification.
  ⇒ Both PPS and SC must approve all Tier 2 publications before submission for external review.

- Tier 3, Ancillary Studies or Methodology: These publications report analyses of results of ancillary studies or focus on methodological issues or any other publications that do not merit a tier 1 or 2 classification.
  ⇒ The PPS must approve all Tier 3 publications before submission for external review.

6 PUBLICATIONS TOPICS AND AUTHORSHIP GUIDELINES

6.1 Publications and Authorship Principles

The publications and authorship guidelines are based on the following principles, which aim to:[1]

(1) Reward individuals for their efforts in obtaining funding (e.g. U34 and U01 grant submissions) and organizing the study's infrastructure (e.g. CC, central laboratory).
(2) Encourage contributions to the successful conduct of the study (e.g. site investigators and research coordinators, active participation in subcommittees).
(3) Generate new and creative ideas to maximize use of trial data.
(4) Ensure that all members of the D2d Research Group view the authorship assignment process as fair and equitable and proportional to the investigators' efforts.
(5) Ensure compliance with the internationally accepted guidelines for authorship established by the International Committee of Medical Journal Editors guidelines.[2]

6.2 Process of generating proposals/manuscripts

- An initial list of proposed manuscripts (tier 1 or tier 2) will be developed by the PPS and EC and circulated to the D2d Study Group.
- Members of the D2d Study Group will be asked to identify 5 of these manuscripts in which they are interested and to rank these choices on a scale from 1 (highest) to 5 (lowest).
- The PPS and EC will create writing groups for each manuscript on this list of proposed manuscripts based on the degree of interest and contributions to the study (see next section).
- Proposals for additional manuscripts may be submitted to PPS by any D2d Research Group member, either by a committee or writing groups, at any time during the study, as described in section 2.4.2.

6.3 Process of assigning writing groups and authorship

- For manuscripts on the list of proposed manuscripts (tier 1 or tier 2), the PPC and EC will review the list of individuals who have expressed interest. For tier 1 proposed manuscripts, the PPC will designate the lead and senior authors and other members of the writing group. For tier 2 proposed manuscripts, the PPC will designate a draft composition of the writing group.
- In most instances, a writing group will be comprised of a lead author, 1-3 senior authors (last, second and third), a statistician and additional co-authors, depending on the manuscript needs.
- Assembling of a group of qualified co-authors and determining the order of authorship should occur early in the process and be transparent. Authorship assignment will reflect the investigators' contribution to the underlying work (site-specific and study-wide contributions, as described below) and to the development of the publication.
- The writing group will meet to discuss writing responsibilities and establish order of authorship. The PPS may mediate disagreements that cannot be resolved by the writing group.
- The lead author, designated by the PPC or by the writing group will then submit the proposed order of authorship for review and approval by the PPC.
- When a proposal for an additional manuscript - namely, one that is not on the original list of proposed manuscripts - is submitted, the lead author will also submit a draft composition of the writing group for review and approval by PPS.
- Depending on the publication category (see above), authorship is designated as follows:
  - Tier 1 publications, the authorship in the journal will be designated as "The D2d Research Group." The writing group (authors) on behalf of D2d Research Group will be named elsewhere, as in a footnote, per *Journal* policy. The complete list of the Research Group will appear either as part of the published manuscript or as supplemental material, per Journal policy.
  - Tier 2 publications, the authorship in the journal will show the writing group (authors), followed by "for the D2d Study Group." The complete list of the Research Group will appear either as part of the published manuscript or as supplemental material, per Journal policy.
  - Tier 3 publications, the authorship in the journal will show the writing group (authors), followed by "and the D2d Study Group." The manuscript should refer to a recent publication that identifies the members of the Study Group.
- In each manuscript, there will be a separate section for acknowledgements, which might include site research coordinators, research assistants, or the entire D2d Research Group.
- Either the writing group or the PPC may initiate a review of the order of authorship if the roles and contributions of the authors change significantly. Authors' names may be deleted from the final list

of authors when these individuals have not participated in the writing and/or analysis of the paper in accordance with the International Committee of Medical Journal Editors guidelines.[2]

6.4 Obligations of authors

An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study.[2] An author must take responsibility for at least one component of the work, should be able to identify who is responsible for each other component, and should ideally be confident in their co-authors' ability and integrity.

Authorship credit is based on all of the following:

1. Substantial contributions to the conception and design, acquisition of data or analysis and interpretation of data.
2. Drafting the article or revising it critically for important intellectual content.
3. Final approval of the version to be published.

⇒ Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.

Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. However, one (or more) of the co-authors will be designated as the individual who accepts primary responsibility for the manuscript.

Authorship in certain D2d publications will be attributed to the D2d Research Group. In those instances, all members of the group who are named as authors should fully meet the above criteria for authorship described above.

Lead authors are responsible for distributing publication materials, including abstracts, manuscripts, presentations, letters to the editors, etc. to all co-authors for review prior to submission to the PPS.

6.5 Method for constructing contributions scores

Authorship assignment will reflect the investigators' contribution to the underlying work, based on site-specific and study-wide criteria (metrics), and to the development of the publication.

6.5.1 Description of Contribution Metrics

The following metrics will be developed and used to determine contributions for each site. Each metric is assigned a different weight (to be determined by the CC and approved by the PPS and EC).[1]

A. Site-specific metrics

1. Enrollment.
   a. Total site enrollment [absolute number].
   b. Relative enrollment (actual to projected [ratio]. *
2. Retention.

a. Observed-to-projected total yearly visits [ratio]. *
3. Data completion and submission to CC.
   i. Timeliness of completion [ratio]. *
   ii. Missing data [ratio]. *

* These metrics will be normalized to the mean of all sites.

B. Study-wide metrics

1. Serving on subcommittees. Not all subcommittees will be weighted equally, e.g. the Safety and Outcomes subcommittee will receive the highest weight followed by Recruitment and Retention, Support and Education, Research Coordinators, Ancillary Studies, Publications and Presentations.
2. Overseeing operations of a core laboratory.

Staff at the CC and the funding agency will be considered for authorship assignments according to interest and level of participation; however, because the above criteria do not apply to these personnel, the EC must approve their participation as authors.

6.5.1 Development of Contribution Score and Assignment of Authorship

The scores for enrollment, retention, data collection, and other trial effort will be summed in a final score. Each site will be ranked on the basis of this final score. Beginning with the highest-ranked site, authorship and order will be established by using the choice of manuscript given by that site's PI first and then proceeding to other study personnel, if available. Points will be considered "spent" from the site's overall score on the basis of authorship position, e.g. 150 points for lead authorship, 100 points for senior authorship, and 50 points for co-authorship. After each author is assigned, the sites will be re-ranked and the next author selected.

7 D2d STUDY BIBLIOGRAPHY

The CC will maintain an official bibliography with all D2d-related publications in a standard citation format and will also maintain a listing of all presentations (written or spoken). The list will be available in the D2d public website with links to PubMed.

The CC will maintain a secure study website for use by the D2d Research Group and its collaborators. The website will provide a downloadable PDF copy of all publications and presentations.

8 REFERENCES

1. Whellan DJ, Ellis SJ, Kraus WE, et al. Method for establishing authorship in a multicenter clinical trial. *Ann Intern Med.* Sep 15 2009;151(6):414-420.
2. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. April 2010 2010.

9 APPENDICES

Appendix 1. Funding Acknowledgment

To be developed prior to the first publication

Appendix 2. Power Point Presentation Template

To be developed prior to the first presentation