Publications, Presentations, and Products Policy

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I. **Purpose**

The National Institutes of Health (NIH) Pragmatic Trials Collaboratory is supported by an NIH-funded cooperative agreement. A principal goal of the NIH Collaboratory is to produce generalizable knowledge by publishing high-quality, timely research findings and perspectives in the peer-reviewed literature; delivering presentations of NIH Collaboratory scholarship in public forums; and sharing guidance, tools, best practices, and other resources for healthcare systems research.

It is recognized that NIH Pragmatic Trials Collaboratory investigators will publish manuscripts, submit abstracts, and deliver presentations that directly reflect NIH Collaboratory activities. Investigators will also publish manuscripts, submit abstracts, and deliver presentations that either mention NIH Collaboratory activities or address topics that are related to NIH Collaboratory activities but are funded from other sources.

The NIH Pragmatic Trials Collaboratory includes the individual Demonstration Projects, the Core Working Groups, and ad hoc working groups, all of which may develop publications, presentations, and other products. Manuscripts, abstracts, presentations, and other products derived from NIH Collaboratory–supported activities will be designated as NIH Collaboratory products.

II. **Definitions**

A. **Demonstration Project Publications and Presentations**

Demonstration Project publications and presentations are manuscripts, abstracts, and presentations that deal directly with knowledge derived from a Demonstration Project. For example, a manuscript, abstract, or presentation that reports methods or results of a Demonstration Project is a Demonstration Project publication or presentation. Review and approval of Demonstration Project publications and presentations will follow the procedures described in Section IV of this policy.

B. **Core Working Group Publications and Presentations**

Core Working Group publications and presentations are manuscripts, abstracts, and presentations produced by a Core Working Group as part of the Core’s efforts to create generalizable knowledge. For example, a manuscript, abstract, or presentation that reports a comparison of methods for validating phenotypes across Demonstration Projects undertaken by members of a Core is a Core Working Group publication or presentation. Review and approval of Core Working Group
publications and presentations will follow the procedures described in Section V of this policy.

C. Guidance Documents

Guidance documents are official statements by the NIH Pragmatic Trials Collaboratory meant to describe procedures or principles for the conduct of healthcare systems research. These documents are intended to have an enduring quality and to represent a synthesis of considerable evidence. Guidance documents may be produced by 1 or more Core Working Groups or by an ad hoc working group. Guidance documents are published on the NIH Collaboratory website. Review and approval of guidance documents will follow the procedures described in Section VI of this policy.

D. Tools, Best Practice Documents, and Other Resources

Tools, best practice documents, and other resources are products that represent a consensus within 1 or more Core Working Groups about approaches to healthcare systems research. Examples include, but are not limited to, checklists, tips and frequently asked questions, executive summaries, and other information resources. Tools, best practice documents, and other resources are intended to evolve and may be subject to frequent revision as lessons emerge from the Demonstration Projects and Core Working Groups. Tools, best practice documents, and other resources are published on the NIH Pragmatic Trials Collaboratory website. Review and approval of tools, best practice documents, and other resources will follow the procedures described in Section VII of this policy.

E. Short Communications

Short communications are products hosted on the NIH Pragmatic Trials Collaboratory website or social media accounts—such as news articles, video and audio recordings, and tweets—about NIH Collaboratory activities and other topics relevant to healthcare systems research. Short communications are produced by the Coordinating Center communications team in consultation with the Coordinating Center leadership. Review and approval of short communications will follow the procedures described in Section VIII of this policy.
III. Publications, Presentations, and Products Committee

A. Members and Decision Making

The Publications, Presentations, and Products Committee ("Publications Committee") consists of Coordinating Center investigators, Demonstration Project representatives, and the NIH project officer and project scientist, as well as nonvoting Coordinating Center staff who serve as committee staff. The Coordinating Center leadership appoints the chair of the committee. Decisions of the committee will be made by majority vote, although consensus will be sought in all cases.

B. Responsibilities

1. The Publications Committee oversees all NIH Pragmatic Trials Collaboratory–supported publication and presentation activities, with final adjudication of decisions made by the Steering Committee as needed. Oversight includes the following specific activities:

   a. The Publications Committee reviews and approves (1) Core Working Group manuscripts before they are submitted and (2) guidance documents before they are published to ensure that descriptions of NIH Pragmatic Trials Collaboratory activities are accurate and to share comments and suggestions. Committee staff review these documents to ensure the use of required acknowledgment and disclaimer language.

   b. Committee staff reviews Demonstration Project manuscripts before they are submitted to ensure the use of required acknowledgment language and to check for mentions of other Demonstration Projects. Committee staff also reviews tools, best practice documents, and other resources before they are published on the NIH Pragmatic Trials Collaboratory website to ensure the use of required acknowledgment and disclaimer language and to check for mentions of Demonstration Projects.

2. The Publications Committee also monitors the overall NIH Pragmatic Trials Collaboratory publications pipeline and proposes new topics for cross-Collaboratory publications. A cross-Collaboratory publication may be prepared by an ad hoc working group or by 1 or more Core Working Groups or Demonstration Project teams.
IV. Demonstration Project Publications and Presentations

A. Authorship

Decisions regarding the content and authorship of Demonstration Project publications and presentations will be made by the individual Demonstration Project steering committee, including NIH staff who provide oversight for the project (when allowed by NIH policy specific to the supporting Institute, Center, or Office).

B. Review

1. Demonstration Project manuscripts will be submitted by the authors to the Coordinating Center (nih-collaboratory@dm.duke.edu) at least 10 business days before the planned submission to allow Publications Committee staff to review the document to ensure the use of required acknowledgment language and to check for mentions of other Demonstration Projects. Committee staff will respond within 10 business days.

Abstracts and presentations should acknowledge NIH Pragmatic Trials Collaboratory support but need not be submitted to the Coordinating Center in advance. See Section IX of this policy for funding acknowledgment language.

2. For draft Demonstration Project manuscripts that include descriptions of or details about a Demonstration Project other than the authors’ own, committee staff will notify the Publications Committee chair and will share the manuscript or other materials with the other Demonstration Project principal investigator. That investigator will be given the opportunity to review the pertinent section for accuracy, comment on the portrayal of the Demonstration Project, and offer corrections of errors, but will not exercise editorial control over other sections of the manuscript. If no response is received from the principal investigator within 10 business days of receiving the manuscript for review, assent and approval will be assumed. In the event of disagreements between the author(s) and the other Demonstration Project principal investigator, the issue will be referred to the chair of the NIH Collaboratory Steering Committee for adjudication.

3. There may be circumstances (for example, if an author is an NIH staff member) wherein an NIH Institute, Center, or Office for a given Demonstration Project would require review of a manuscript, abstract, or presentation before its submission. Authors are expected to work with NIH...
staff to determine whether such a review is required and, if so, to ensure that the requirement is addressed before submission.

4. Final editorial authority and the decision to publish will reside with the Demonstration Project steering committee, including NIH staff who provide oversight for the project. The Publications Committee will provide advice, suggestions, and assistance with dissemination as needed.

5. Other manuscripts, abstracts, and presentations arising from Demonstration Projects without specific aims of being designated as NIH Pragmatic Trials Collaboratory publications or presentations will be provided by Demonstration Project investigators in a listing submitted biannually to the Coordinating Center. The Demonstration Project investigator or Publications Committee chair may request that a manuscript be shared for comment due to high interest.

6. All Demonstration Project manuscripts submitted to the Coordinating Center before publication will remain confidential and will not be shared outside the Publications Committee membership and staff, Demonstration Project principal investigators (if applicable), Coordinating Center principal investigators, and the author(s).

C. After Publication or Presentation

1. Once a Demonstration Project manuscript, abstract, or presentation has been accepted for publication or presentation, the lead author or their designee will inform the Coordinating Center staff and provide them with a final copy of the accepted publication or presentation.

2. Demonstration Project principal investigators or their designees will submit quarterly updates to Coordinating Center about all publication and presentation activity related to the project.

V. Core Working Group Publications and Presentations

A. Authorship

Decisions regarding the content and authorship of Core Working Group publications and presentations will be made by the members of the Core Working Group(s) involved in creation of the work. All members of the respective Core Working Group(s) will be given an opportunity for comment. If 10 business days pass without feedback, assent to that version of the manuscript will be assumed.
B. Review

1. Core Working Group manuscripts will be submitted by the author(s) to the Coordinating Center (nih-collaboratory@dm.duke.edu) for delivery to the Publications Committee staff, who will have 10 business days to collect and forward comments and suggestions from (a) Core Working Group members, (b) Publications Committee members, and (c) any additional Coordinating Center members involved. There may be circumstances (for example, if an author is an NIH staff member) wherein an NIH Institute, Center, or Office would require review before submission. Authors are expected to work with NIH staff to determine whether such a review is required and, if so, to ensure that the requirement is addressed before submission.

Abstracts and presentations should acknowledge NIH Pragmatic Trials Collaboratory support but need not be submitted to the Coordinating Center in advance. See Section IX of this policy for funding acknowledgment language.

2. For draft Core Working Group manuscripts that include descriptions of or details about a Demonstration Project, the Publications Committee staff will share the manuscript with the Demonstration Project principal investigator. The Demonstration Project principal investigator will be given the opportunity to review the pertinent section for accuracy, comment on the portrayal of the Demonstration Project, and offer corrections of errors, but will not exercise editorial control over other sections of the manuscript. If no response is received from the Demonstration Project principal investigator within 10 business days of receiving the manuscript for review, assent and approval will be assumed. In the event of disagreements between the author(s) and the Demonstration Project principal investigator, the issue will be referred to the chair of the NIH Collaboratory Steering Committee for adjudication.

3. An additional 10 days may be taken by the Publications Committee after comments are generated to adjudicate any resulting editorial changes.
   a. Where intractable differences of opinion remain, suggested changes from all sides will be forwarded to the designated coauthors.
   b. Comments from any Publications Committee member, NIH or otherwise, will not constitute official positions of the NIH.

4. Final editorial authority and the decision to publish will reside with the designated coauthors, although the Publications Committee will have the
right to vote on the designation of the final proposed manuscript as an NIH Pragmatic Trials Collaboratory publication or presentation.

a. Manuscripts, abstracts, and presentations that are not designated as NIH Pragmatic Trials Collaboratory publications or presentations will not be listed on the NIH Pragmatic Trials Collaboratory website and will not benefit directly from any public relations or news items published on the NIH Pragmatic Trials Collaboratory website.

5. In the event that authors of a publication must meet an impending deadline for a special issue or call for papers or respond to an invitation to submit within a brief period of time, authors should contact the Coordinating Center to request expedited review of the manuscript. If an expedited review is not possible before submission, the authors will send the manuscript to the Coordinating Center within 10 business days after submission; the Publications Committee will still consider whether the manuscript will be designated as an NIH Pragmatic Trials Collaboratory publication.

6. All Core Working Group manuscripts submitted to the Coordinating Center before publication will remain confidential and will not be shared outside the Publications Committee membership and staff, Demonstration Project principal investigators (if applicable), Coordinating Center principal investigators, and the author(s).

C. After Publication

Once a Core Working Group manuscript, abstract, or presentation has been accepted for publication or presentation, the lead author or their designee will inform the Coordinating Center staff, who will notify the NIH program official and the Publications Committee staff.

VI. Core Working Group Guidance Documents

A. Authorship

Decisions regarding the content and authorship of guidance documents will be made by the members of the Core Working Group(s) or ad hoc working group involved in creation of the work. All members of the respective working group(s) will be given an opportunity for comment. If 10 business days pass without feedback, assent to that version of the guidance document will be assumed.
B. Review

1. Guidance documents will be submitted by the author(s) to the Coordinating Center (nih-collaboratory@dm.duke.edu) for delivery to the Publications Committee staff, who will have 10 business days to collect and forward comments and suggestions from (a) working group members, (b) Publications Committee members, and (c) any additional Coordinating Center members involved. There may be circumstances (for example, if an author is an NIH staff member) wherein an NIH Institute, Center, or Office would require review before publication of the guidance document. Authors are expected to work with NIH staff to determine whether such a review is required and, if so, to ensure that the requirement is addressed before submission.

2. For guidance documents that include descriptions of or details about an ongoing or completed Demonstration Project, the Publications Committee staff will share the document with the Demonstration Project principal investigator. The Demonstration Project principal investigator will be given the opportunity to review the pertinent section for accuracy, comment on the portrayal of the Demonstration Project, and offer corrections of errors, but will not otherwise exercise editorial control over the document. If no response is received from the principal investigator within 10 business days of receiving the guidance document, assent and approval will be assumed. In the event of disagreements between the author(s) and the Demonstration Project principal investigator, the issue will be referred to the chair of the NIH Collaboratory Steering Committee for adjudication.

3. An additional 10 days may be taken by the Publications Committee after comments are generated to adjudicate any resulting editorial changes.

   a. Where intractable differences of opinion remain, suggested changes from all sides will be forwarded to the author(s).

   b. Comments from any Publications Committee member, NIH or otherwise, will not constitute official positions of the NIH.

4. Final editorial authority and the decision to publish the guidance document will reside with the author(s).
VII. Core Working Group Tools, Best Practice Documents, and Other Resources

A. Authorship

Decisions regarding the content (and authorship, if applicable) of tools, best practice documents, and other resources will be made by the members of the Core Working Group(s) or ad hoc working group involved in the creation of the work. All members of the respective Core Working Group(s) or ad hoc working group will be given an opportunity for comment. If 10 business days pass without feedback, assent to that version of the document will be assumed.

B. Review

1. Tools, best practice documents, and other resources will be submitted by the authors to the Coordinating Center (nih-collaboratory@dm.duke.edu) for delivery to Publications Committee staff at least 10 business days before publication to allow staff to review the document to ensure the use of required disclaimer language, if applicable, and to check for mentions of Demonstration Projects. The committee staff will respond within 10 business days.

2. For tools, best practice documents, and other resources that include descriptions of or details about an ongoing or completed Demonstration Project, committee staff will share the document with the Demonstration Project principal investigator. The Demonstration Project principal investigator will be given the opportunity to review the pertinent section for accuracy, comment on the portrayal of the Demonstration Project, and offer corrections of errors, but will not exercise editorial control over other sections of the document. If no response is received from the principal investigator within 10 business days of receiving the document, assent and approval will be assumed. In the event of disagreements between the author(s) and the Demonstration Project principal investigator, the issue will be referred to the chair of the NIH Collaboratory Steering Committee for adjudication.

3. There may be circumstances (for example, if an author is an NIH staff member) wherein an NIH Institute, Center, or Office for a given Demonstration Project would require review of a best practice document before its publication. Authors are expected to work with NIH staff to determine whether such a review is required and, if so, to ensure that the requirement is addressed before publication.
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4. Final editorial authority and the decision to publish will reside with the authors.

VIII. Short Communications by the Coordinating Center

Short communications are produced by the Coordinating Center communications team in consultation with the Coordinating Center leadership. They are prepared in accordance with the Coordinating Center staff’s relevant operational processes.

IX. Acknowledgment of NIH Pragmatic Trials Collaboratory Support

1. All manuscripts, abstracts, and presentations derived from the work of one or more Core Working Groups or the Coordinating Center should include the following acknowledgment:

“This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through cooperative agreement U24AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), the National Institute on Aging (NIA), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Nursing Research (NINR), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP). This work was also supported by the NIH through the NIH HEAL Initiative under award number U24AT010961. [If supplemental funding was provided for specific activities, then the Institute, Center, or Office providing the support should be acknowledged here.] The content is solely the responsibility of the authors and does not necessarily represent the official views of the NCCIH, NIAID, NCI, NIA, NHLBI, NINR, NIMHD, NIAMS, OBSSR, or ODP, or the NIH or its HEAL Initiative.”

2. Manuscripts, abstracts, and presentations derived from one or more Demonstration Projects:

a. All manuscripts, abstracts, and presentations derived from one or more NIH Pragmatic Trials Collaboratory Demonstration Projects should include the following acknowledgment:

“This work was supported within the National Institutes of Health
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(Additional text from the document)
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(NIH) Pragmatic Trials Collaboratory through cooperative agreement U24AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), the National Institute on Aging (NIA), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Nursing Research (NINR), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP), and through cooperative agreement [UG3/UH3 grant number] from the [Institute, Center, or Office providing funding or oversight]. This work was also supported by the NIH through the NIH HEAL Initiative under award number U24AT010961. [If supplemental funding was provided for specific activities, then the Institute, Center, or Office providing the support should be acknowledged here.] The content is solely the responsibility of the authors and does not necessarily represent the official views of the [Institute, Center, or Office providing funding or oversight] or the NCCIH, NIAID, NCI, NIA, NHLBI, NINR, NIMHD, NIAMS, OBSSR, or ODP, or the NIH or its HEAL Initiative.

b. All manuscripts, abstracts, and presentations supported by the Coordinating Center and one or more PRISM Demonstration Projects should include the following acknowledgment:

“This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through cooperative agreement U24AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), the National Institute on Aging (NIA), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Nursing Research (NINR), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP), and by the NIH through the NIH HEAL Initiative under award number [UG3/UH3 grant number] administered by the [Institute, Center, or Office providing funding or oversight]. This work was also supported by the NIH through the NIH HEAL Initiative under award number U24AT010961. [If supplemental funding was provided for specific activities, then the Institute, Center, or Office providing the
4. Manuscripts that cite **multiple sources of support** (for example, a project supported by the Coordinating Center and one or more NIH Institutes, Centers, or Offices) should list funding sources in declining order of proportional support for the given project.

5. Before issuing a press release concerning results, presentations, or publications derived from this research, authors should notify the relevant NIH Institute, Center, or Office in advance to allow for coordination.