I. Publication/Presentation Designations
As the Health Care Systems Research Collaboratory ("the Collaboratory") is an NIH-funded Cooperative Agreement, a principal goal of the Collaboratory is to publish high-quality and timely manuscripts that advance knowledge in the peer-reviewed literature, as well as deliver presentations of Collaboratory findings in a public forum.

A. It is recognized that Collaboratory investigators will publish manuscripts and deliver presentations that directly reflect Collaboratory-related activities and others that may either mention the Collaboratory or address topics related to Collaboratory activities, but that will be funded from other sources.

B. Manuscripts, abstracts and presentations derived from Collaboratory-funded activities are designated as “Collaboratory” manuscripts, abstracts, and presentations.

C. The Collaboratory includes both Working Group/Cores that work closely with the Collaboratory Coordinating Center (CCC) and study teams across Demonstration Projects, and individual Demonstration Projects, which will develop publications and presentations.

1. A “Working Group/Core manuscript, abstract, or presentation” describes the product of the Working Group/Core (WG/C) as part of its efforts to create generalizable knowledge. For example, a comparison of methods for validating phenotypes across Demonstration Projects undertaken by members of a WG/C, would be a WG/C manuscript, abstract, or presentation.

2. A “Demonstration Project manuscript, abstract or presentation” deals directly with knowledge derived from a specific Collaboratory Demonstration Project. The methods or results of a specific clinical trial would constitute a Demonstration Project manuscript, abstract, or presentation.

The procedures for review of publications and presentations for the different Collaboratory groups are outlined in items III and IV.

II. Collaboratory Products, Publications & Presentations Committee (C3PC)
A. This committee will comprise representation from CCC faculty, Demonstration Project PIs, and NIH representatives, as well as nonvoting Collaboratory
Coordinating Center staff. A Chair will be appointed by consensus, rotating annually. Decisions will be made by majority, although consensus will be sought in all cases.

B. The C3PC oversees all Collaboratory-funded publication and presentation activities, with final adjudication of decisions by the Steering Committee as needed. The C3PC approves 1) proposed publications and abstracts slated for submission; 2) completed manuscripts before they are submitted for publication; and 3) presentations before they are made in a public forum.

III. Procedure for Working Group/Core Publications & Presentations
A. Decisions regarding content and authorship of publications and presentations will be approved by members of the respective WG/C.
   1. All WG/C members will be given an opportunity for comment. If the interval specified for comments passes without feedback (2 weeks [10 business days]), assent to that version of the manuscript is assumed.

B. Manuscripts will be submitted by the first author to the C3PC Chair (or the Chair’s designee), who will have 2 weeks (10 business days) to collect and forward comments and suggestions from: a) WG/C members, b) C3PC members, c) any additional CCC members involved. There may be circumstances (for example, if an author is an NIH staff member) wherein an NIH Institute/Center (IC) for a given manuscript, abstract, or presentation would require review prior to its submission. WG/C authors are expected to work with NIH staff to determine whether such an IC review is required, and if so, to ensure that the requirement is addressed prior to submission for publication.

C. For Core/Working Group draft manuscripts, abstracts, or public presentations that include descriptions of or details about an ongoing HCS Research Collaboratory Demonstration Project, a draft version of the manuscript or other materials will also be routed to Coordinating Center staff for forwarding to the Demonstration Project Principal Investigator at least 2 weeks prior to initial manuscript submission (or resubmission involving substantive changes to the relevant section). Demonstration Project Principal Investigators will be given the opportunity to review the pertinent section for accuracy, comment on the portrayal of the Demonstration Project, and offer corrections for any errors, but will not exercise any editorial control over other sections of the manuscript. If no response is received from the Principal Investigator within 2 weeks of receiving the manuscript for review, assent and approval will be assumed. In the event of disagreements between the author(s) and the Demonstration Principal Investigator, the issue will be referred to the Collaboratory Steering Committee Chair for adjudication.

D. An additional 10 days may be taken by C3PC after comments are generated to adjudicate any resulting editorial changes.
   1. Where intractable differences of opinion remain, suggested changes from all
sides will be forwarded to the designated co-authors.

2. Comments from any C3PC member, NIH or otherwise, will not constitute official positions of the NIH.

E. Final editorial authority and the decision to publish will reside with the designated co-authors, although the C3PC will have the right to vote on the designation of the final proposed manuscript as a “Collaboratory Publication or Presentation.”

1. Publications and presentations that are not designated “Collaboratory” will not be posted on the Collaboratory website under “manuscripts,” nor benefit directly from any public relations or news brief items published on the Collaboratory website.

F. Once a WG/C manuscript has been accepted for publication, the lead author or their designee will inform the NIH Program Official for the CCC and the C3PC Chair and/or designee.

G. In the event that authors of a publication or presentation must meet an impending deadline for a special issue or call for papers, or respond to an invitation to publish within a brief period of time, authors should contact the C3PC Chair or designee to request expedited review of their manuscript, abstract, or presentation. If an expedited review is not possible prior to submission for publication, the co-authors may send such manuscripts to the C3PC within 2 weeks (10 business days) of submission; the C3PC will still consider whether the manuscript is a “Collaboratory” product.

IV. Procedure for Demonstration Project Publications & Presentations

A. Decisions regarding the content and authorship of these publications and presentations will be made by the individual Demonstration Project Steering Committee, including NIH staff that provide oversight for the project.

B. Manuscripts intended as “Collaboratory” manuscripts should be sent to the C3PC Chair and/or designee by the first author at least 2 weeks (10 business days) prior to planned submission for review and comment. The C3PC will respond within 2 weeks (10 business days).

C. Abstracts and presentations intended as Collaboratory abstracts and presentations should be sent to the C3PC Chair and/or designee by the first author 2 weeks prior to planned submission for review and comment.

D. For Demonstration Project draft manuscripts, abstracts, or public presentations that include descriptions of or details about an ongoing HCS Research Collaboratory Demonstration Project other than the author’s own, a draft version of the manuscript or other materials will also be routed to Coordinating Center staff for forwarding to the Demonstration Project Principal Investigator at least 2 weeks prior to initial manuscript submission (or resubmission involving substantive changes to the relevant section), as detailed in Section

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III.B above.

E. There may be circumstances wherein an IC for a given Demonstration Project would require review of a manuscript, abstract, or presentation prior to its submission. Authors are expected to work with their respective Program Officials to determine whether such an IC review is required, and if so, to ensure that the requirement is addressed prior to its submission.

F. Final editorial authority and decision to publish will reside with the Demonstration Project Steering Committee, including NIH staff that provide oversight for the project. The C3PC will provide advice, suggestions, and assistance with dissemination as needed.

G. Once the Collaboratory Demonstration Project manuscript, abstract, or presentation has been accepted for publication or presentation, the first author will inform the NIH Program Official and the C3PC Chair and/or designee, and provide them with a final copy of the accepted publication or presentation.

H. Other manuscripts, abstracts, and presentations arising from the Demonstration Projects, without specific aims of becoming “Collaboratory” publications or presentations will be provided by Demonstration Project investigators in a listing sent biannually to the C3PC.

   1. The Demonstration Project Lead or C3PC Chair may request a manuscript be shared for comment due to high interest.

All manuscripts submitted to the C3PC prior to publication will remain confidential and will not be shared outside the C3PC members, WG/C members, CCC principal investigators, and manuscript co-authors.

V. Acknowledgment of Collaboratory Support for Collaboratory Manuscripts, Abstracts & Presentations

A. All manuscripts, abstracts, or presentations derived or supported solely by the Collaboratory Coordinating Center Working Group must include the following acknowledgment:

   This work is supported by the National Institutes of Health (NIH) Common Fund, through cooperative agreement U24AT009676 from the Office of Strategic Coordination within the Office of the NIH Director. The views presented here are solely the responsibility of the authors and do not necessarily represent the official views of the National Institutes of Health.

B. All manuscripts, abstracts, or presentations supported by the Collaboratory Coordinating Center and a Collaboratory Demonstration Project (UG3/UH3) should include the following acknowledgment:

   This work is supported by the National Institutes of Health (NIH) Common Fund, through cooperative agreement U24AT009676 from the Office of Strategic Coordination within the Office of the NIH Director and cooperative agreement [UG3 NUMBER/UH3 NUMBER] from the [NIH INSTITUTE, CENTER, OR
C. Projects with support from NIH Institutes, Centers, and Offices (ICO) should include the statement:

Research reported in this publication was supported by [GRANT NUMBER] from the [RELEVANT INSTITUTE/CENTER/OFFICE]. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

D. Manuscripts that cite multiple sources of support (for example, a project supported by the Collaboratory Coordinating Center U24 grant and one or more ICO) should list funding sources in declining order of proportional support for the given project/manuscript:

Research reported in this publication was supported by [GRANT NUMBER] from the [INSTITUTE/CENTER/OFFICE]. Support was also provided by the National Institutes of Health (NIH) Common Fund, through a cooperative agreement U24AT009676 from the Office of Strategic Coordination within the Office of the NIH Director. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

E. Prior to issuing a press release concerning results, presentations, or publications derived from this research, please notify the NIH IC in advance to allow for coordination.