Diversity Program Consortium Guidelines for Publications, Presentations and the Public Release of Consortium-Wide Data

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1. Overview and Purpose

In response to recommendations from the NIH Advisory Committee to the Director (ACD) Working Group on Diversity in the Biomedical Research Workforce, the Enhancing the Diversity of the NIH-funded Workforce Program was established in 2014. The program comprises three initiatives funded through an NIH cooperative agreement mechanism: (1) Building Infrastructure Leading to Diversity (BUILD); (2) National Research Mentoring Network (NRMN) and (3) Coordination and Evaluation Center (CEC). The initiative is a national collaborative through which awardees work collectively as the NIH Diversity Program Consortium (DPC). The long-term goal of the DPC is to find effective methods to enhance the diversity of the biomedical research workforce.

The purpose of these guidelines for DPC Publications, Presentations, and the Public Release of Consortium-Wide Data is to encourage and facilitate the development of high-impact, rigorous consortium products while ensuring the appropriate use of data, timely completion of projects, and adherence to the principles of responsible authorship. These guidelines are in alignment with the DPC Data Sharing Agreement, a document that details the types and appropriate use of consortium-wide data. It is the responsibility of each DPC contact Principal Investigator to ensure that all professionals at the awardee site involved with DPC publications and presentations agree to adhere to these guidelines.

A listing of the site-level and consortium-wide publications are provided on the <u>NIGMS</u> and <u>CEC</u> websites. Individual awardees are encouraged to post site-level materials (e.g., presentations, meeting abstracts, etc.) on the <u>DPC</u> intranet.

2. Publications and Products Subcommittee (PPsC) Administrative Structure

Publications and Products Subcommittee. This Executive Steering Committee (ESC) subcommittee ensures compliance with the guidelines outlined in this document. The PPsC meets monthly. Quorum is two-thirds of the voting members, and the outcome of a vote is determined by simple majority of the number of votes cast. All decisions by this subcommittee may be appealed to the ESC. A PPsC representative provides routine progress reports to the ESC. Membership is as defined below:

- *Voting members*: The PPsC has voting representation from each of the DPC awardees that have participated in consortium-wide data collection efforts from Phase I (RFA-RM-13-017, RFA-RM-13-016, RFA-RM-13-015) and Phase II (RFA-RM-18-006, RFA-RM-18-005) as well as one voting member from the NIH. While multiple representatives from each awardee site may attend the monthly meetings, each awardee listed above has one vote. The roster of voting members is available on the PPsC intranet site.
- PPsC Leadership: The voting members of the subcommittee nominate individuals to serve as the PPsC Chair and Associate Chair. Typically, the Chair and Associate Chair rotate annually, with the Associate Chair becoming the Chair and a new Associate Chair being elected. When elections are held, the PPsC Coordinator collects nominations for the leadership position(s) and notifies the individual subcommittee members of their nominations. The individuals have an opportunity to accept or decline the nomination, and then the voting members of the subcommittee are invited to cast their votes. The PPsC Chair and Associate Chair are listed on the PPsC intranet site.
- PPsC Coordinator: The CEC-based PPsC Coordinator provides support to the PPsC and the
 <u>Consortium Writing Groups</u>, manages the proposal process, maintains the archive of <u>PPsC</u>
 <u>documents</u>, organizes the PPsC committee meetings with the Chair and Associate Chair, and
 oversees the reporting of minutes, actions, and follow-up activities.
- Consortium Writing Groups: The DPC writing groups self-form to write manuscripts on consortium-wide topics. The writing groups must have the appropriate expertise to conduct rigorous data analysis and to develop a manuscript. Each group should have representation of all DPC-relevant awardees; however, individual sites may choose to not participate. External collaborators may be included among the authors to bring the requisite skills to the team. Each of the writing groups has a lead author who is responsible for leading the group and adhering to the timeline agreed upon in the manuscript proposal (see below). The PPsC must be notified if the composition of the group or if the topic changes. If topics from different consortium writing groups overlap, the PPsC will attempt to resolve the situation informally with the lead authors of the involved writing groups. If the mediation fails, the issue will be brought to the ESC for resolution. If a writing group is consistently behind its timeline, members of the team will be asked to appoint a new lead author. If no member of the team is willing or able to assume that role, the opportunity will be opened to the DPC.
- *Lead Author:* The lead author is responsible for overseeing all components of the product. The responsibilities include the following:
 - Ensuring the integrity of the work from conception to publication or public release.
 - Communicating all expectations with co-authors about timeline expectations for completion of the manuscript.
 - Ensuring that all relevant individuals receive and review the most up-to-date document(s).
 - Creating an "Acknowledgements" section using DPC guidelines (see below).
 - Attend the monthly PPsC meeting to report progress.
 - Lead no more than one consortium-wide paper at a time.
- Other: The PPsC may invite ad hoc ex officio members as needed for the proposal review process. Lists of suggested ad hoc ex officio members are available on the PPsC Intranet site.

3. PPsC Role in the Publication Strategic Plan

The publication strategic plan allows the DPC to develop priorities, prevent overlap, and ensure the timely completion of high-quality scientific products. The PPsC, with the administrative support of the CEC, is responsible for executing aspects of the strategic plan, including the following:

- Maintaining a Master List of potential consortium-wide and sub-consortium hypotheses
- Annotating all topics on which writing groups are working
- Recruiting writing groups for high priority topics
- Managing the approval process for consortium-wide studies
- Monitoring data requests for consortium-wide studies
- Indicating the current progress within timelines for consortium-wide studies
- Ensuring the use of DPC standards for authorship and acknowledgements
- Maintaining a repository of consortium products on the intranet

4. Obtaining approval for the use of consortium-wide data

Any use of consortium-wide data in publications, presentations, and grant proposals must go through an approval process to ensure fairness and prevent overlap of efforts within the DPC. The submission process to access consortium-wide data is detailed in Section 6 of this document. Briefly, authors submit proposals to the PPsC and the proposals are vetted by the PPsC. If approved, the CEC Data Coordination Core provides cleaned, de-identified data through a secure portal as described in the Data Sharing Agreement. The timeline for providing the data depends on the extent of the request, and teams are advised to consider this factor when developing data requests and publication timelines. When products are ready for submission or public posting, they must be submitted to the CEC PPsC Coordinator, who will send it out for review to ensure the authors adhered to their original proposal. Authors are encouraged to use the DPC Style Guide and must use the standardized language below for citing the consortium-wide data as detailed below in the authorship and acknowledgement sections below.

5. Types of products using consortium data

There are several general classifications of products derived from DPC data with different approval processes for each category: (1) consortium-wide research, (2) consortium-wide exploratory analyses, (3) consortium-wide evaluation, (4) individual awardee or site-level research, (5) sub-consortium research, (6) DPC research conducted by non-DPC members, and (7) marketing/communications.

- 5.1. Consortium-Wide Research/Requesting Consortium-Wide Data for Use in Grant Proposals: Research in which part or all of the data are derived from consortium-wide data as defined in the <u>Data Sharing Agreement</u>. The research requires approval from the PPsC, upon which the research topic will be annotated on the <u>Master List</u>.
- 5.2. Consortium-Wide Exploratory Analyses: A preliminary analysis in which part or all of the data are derived from consortium-wide data as defined in the <u>Data Sharing Agreement</u>. The activity requires approval from the PPsC and can only be requested by DPC members. In general, exploratory analyses are used to obtain descriptive and/or univariate statistics, trending, and/or data comparisons that may be used to refine hypothesis-driven questions related to the DPC Hallmarks of Success. Upon approval, the analysis topic will be annotated on the <u>Master List</u>. After completing the approved exploratory data analysis and refining the hypothesis-driven questions, the authors must submit an application for Consortium-Wide Research before proceeding with manuscript development. Groups should note that priority for delivering data sets will be given to proposals for Consortium-Wide Research rather than to Exploratory Analyses.

- 5.3. Consortium-Wide Evaluation Products: Evaluation products produced by the CEC as defined in the <u>Data Sharing Agreement</u>. The CEC is responsible for disseminating <u>consortium-wide evaluation products</u> that map to the <u>Hallmarks of Success</u>. The consortium-wide evaluation product list was approved by the ESC in March 2019. Individual evaluation products from the approved list do not require additional PPsC approval; however, the CEC is required to notify the PPsC if the scope of the product deviates from the original description or of the intent to publish. The NIH Project Scientist for the CEC provides input on these products throughout production and ensures the finalized products adhere to the original description.
- 5.4. Site-Level Research: Any research conducted by a DPC awardee related to the scope of the awards as defined in the <u>Data Sharing Agreement</u>. No pre-publication approval is required; however, awardees are strongly encouraged to notify the PPsC of the intent to publish and the topic should be annotated on the <u>Master List</u> to enhance communication, promote collaborations, and avoid competition.
- 5.5. Sub-Consortium Research: Collaborations on consortium-related topics that include two or more DPC awardees but are not consortium-wide collaborations. Collaborations using shared site-level data do not require approval; however, the collaborators are required to notify the PPsC of the intent to publish and the collaboration should be annotated on the Master List. Collaborations using consortium-wide data (e.g., as a comparator group) must go through the approval procedures detailed in section 5.1 of this document.
- 5.6. Research conducted by non-DPC members using de-identified consortium data. Outside parties must adhere to the <u>Data Sharing Agreement</u> and are required to identify a DPC sponsor, gain PPsC approval, and obtain an additional level of review by the ESC. The inclusion of a DPC member sponsor ensures there is a co-author with IRB coverage and the necessary contextual framework to optimally design analyses and interpret findings. The research will be annotated on the <u>Master List</u>.
- 5.7. Marketing/Communications Materials. The PPsC does not oversee promotional and outreach material related to DPC activities (e.g., non-peer-reviewed publications, press releases, and internal presentations of DPC activities). Awardees are encouraged to use the agreed upon practices developed by the Communications Working Group for these types of materials.

6. Process of PPsC Review of Proposals and Products using Consortium-Wide Data

Authors of potential publications/grant proposals or presentations using consortium-wide data must submit documents to the PPsC. For manuscript publications and public data briefs, two reviews are required: a pre-approval to obtain consortium-wide data and again before submission or public release. The process of review is as follows:

Preapproval process:

- 1. Authors of potential publications/grant proposals or presentations using consortium-wide data must submit a <u>proposal</u> for approval by the PPsC. Authors are encouraged to consult their NIH Project Scientist to get input prior to submission to the PPsC.
- 2. The PPsC Coordinator, in consultation with the chairs, will appoint two to three primary reviewers (ideally, the reviewers should be subcommittee members, consortium members, or on occasion, *ad hoc* advisors with the appropriate expertise). To avoid the appearance of bias, the

reviewers should not be members of the writing group that submitted the proposal, or from the same DPC awardee site as the lead author of the writing group.

- 3. The members of the review panel will each prepare and send the PPsC Coordinator a critique of the proposal using the <u>reviewer's checklist for preapprovals</u>. The PPsC Coordinator will send out the critiques along with the preapproval proposal in advance of the next PPsC meeting. The PPsC representatives will be given a deadline (typically 1 week) to submit comments or critiques.
- 4. For normal submissions, the primary reviewers will lead the discussion regarding the proposal at the next PPsC call. For expedited submissions, an *ad hoc* meeting of the PPsC will be convened (or via email, if necessary). Meeting participants will be invited to participate in the discussion. All voting members will cast a vote. There are four possible dispositions:
 - a. Approval of the proposal to proceed as submitted.
 - b. Provisional approval, pending revisions and re-review by the PPsC.
 - c. Conflicts with a previously approved proposal. If the proposal overlaps with another project already in progress, the writing group lead authors will be informed so that a collaboration can be discussed. If a collaboration is accepted by both parties, the writing group lead authors will send the PPsC a letter describing the roles and responsibilities of each party. Conflicts that cannot be resolved will be brought before the ESC.
 - d. Non-acceptance of the proposal, but with recommendations for revisions.
- 5. The PPsC Coordinator is responsible for communicating the review decision to the authors together with a summary of the review. If the decision is contested by the authors, the PPsC Coordinator will report this outcome to the ESC for adjudication. The PPsC Coordinator will provide a copy of the proposal, a summary critique, and a rebuttal to the ESC to inform the vote.
- 6. If the <u>proposal is exploratory</u>, the authors must submit their hypothesis-driven research project for approval through this process before proceeding with writing.

Before manuscript submission or public release of data briefs:

- The authors must submit the final product along with a <u>submission checklist</u> to a DPC NIH
 Official and to the PPsC Coordinator prior to submission or public release to confirm that the
 product adheres to the original proposal and follows the authorship and acknowledgment
 guidelines in this document.
- 2. If the manuscript identifies individual sites, the submission must include approval from each of the PIs of sites/programs specifically named in the manuscript/product.
- 3. The product is either approved for submission or release or returned for revisions.
- 4. The authority to grant final approval for release of publications or proposals using DPC consortium-wide data rests with the PPsC, or the ESC in cases of conflict.

7. Summary of Consortium Products and Required Approvals

Type of Consortium Product	Consortium- Wide Data?	Level of Approval	Notify PPsC?	On Master List?
Consortium-Wide Hypothesis-Driven	Yes	PPsC	Yes	Yes
Consortium-Wide Exploratory*	Yes	PPsC	Yes	Yes
CEC Evaluation Products	Yes	ESC	Yes	Yes
Site-Level	No	None	Encouraged	Encouraged
Sub-Consortium	No	None	Yes	Yes
Sub-Consortium, using CWEP data (e.g. for comparisons/ analysis)	Yes	PPsC	Yes	Yes
Conducted by Non-DPC member with a DPC Sponsor	Yes	PPsC/ESC	Yes	Yes
Marketing/Communications	No	None	No	No

^{*}Must submit a new proposal once the research question or hypothesis has been identified

8. DPC Policies for Authorship, Conflict of Interest, and Publication Costs

These practices ensure equitable and appropriate attribution of credit to all participating individuals across the DPC. The authorship policy of the DPC must achieve two somewhat conflicting goals. First, it is recognized that the findings of consortium-wide studies are derived from the efforts of the entire consortium. Thus, all consortium-wide reports, of any type, must give recognition to all DPC members. On the other hand, it is recognized that the preparation of a manuscript places special demands on the assigned writing group, especially on the lead author. Additionally, recognition of special effort and achievement is important in the authors' professional careers and is a significant motivating factor that will help assure prompt completion of writing assignments and timely publication of the results of consortium-wide studies. The DPC authorship policy attempts to recognize each of these goals.

Authorship

Authorship will be based on the following criteria (adapted from <u>ICMJE recommendations</u> and Harvard Medical School Publication Guidelines):

- 1. Everyone who is listed as an author should have made a substantial, direct, intellectual contribution to the work (i.e., substantial contributions to the conception or design of the work, *or* the acquisition, analysis or interpretation of the data for the work); AND
- 2. All authors must participate in the writing and revising of the document as well as the approval of the final content; AND
- 3. All authors must be accountable for the content in ensuring the accuracy and integrity. In certain cases, when an author provides highly specialized expertise, the individual's contributions and responsibility may be limited to specific aspects of the work (e.g., statistical analyses, etc.).

Those designated as authors should meet ALL criteria for authorship, and all who meet the four criteria should be identified as authors. Each journal has specific guidelines for authorship. Any additional guidelines required by the journal should be added to the general authorship guideline above when appropriate. Any dispute about authorship will be resolved by the PPsC after consultation with the ESC.

Order of Authorship (adapted from Harvard Medical School Publication Guidelines):

The authors should decide the order of authorship together. The primary author should prepare a concise, written description of how order of authorship was decided to be included in the manuscript. It is recommended that the authors should appear in descending order of contribution, placing the

person who took the lead in writing the manuscript first. The remaining authors should appear in alphabetical or random order if the contributions were equal.

Authors must verify in the proposal form that there are no conflicts of interest (i.e., no author will derive personal benefit from the outcomes of the research).

Publication costs must be decided upon early in the process and described in the proposal form (typically, the lead author is responsible for the publication costs).

9. DPC Policies for Acknowledgements

The DPC does not permit inclusion of 'honorary' authors; however, the lead author may include an acknowledgement of contributors who do not meet the criteria for authorship (see above), for example, a person who provided purely technical help or writing assistance; a mentor who provided only general support; or colleagues, reviewers and staff who do not qualify as authors. The acknowledgement should include the individual's identity, their organizational affiliation, and their function or contribution to the paper (e.g., "served as scientific advisor," or "critically reviewed the research application proposal"). Financial and material support should be acknowledged (see below). The lead author is responsible for ensuring individuals identified in the acknowledgement section have an opportunity to review the draft and consent to being listed on the paper prior to submitting the final draft.

A **DPC Participant List** should be acknowledged in all publications using consortium-wide data (see below). The DPC Participant List is a roster of all professionals that have participated in the consortium-wide effort for a minimum of one year. The participants for each consortium awardee will be listed together, with the site Principal Investigator(s) listed first as contact PI or co-PIs, followed by the other site staff listed alphabetically. Each participant will be listed only by his/her professional and academic degrees, not by the specific position that she/he held in the study. The awardees will be listed in the following order: BUILD sites (the name of the awardee institution, in alphabetical order), NRMN Phase I, NRMN Phase II, CEC, and NIH. Each awardee is responsible for providing their Participant List to the CEC. The CEC will maintain the lists on a public facing website. Prior to any consortium-wide publications, each awardee will be asked to confirm and update the listing of the personnel from that site in the DPC Participant List.

NIH Requirements

Before submitting the article for publication, review the journal's instructions to authors for any specific information or instructions related to the <u>NIH Public Access Policy</u>. The publisher's copyright transfer or publication agreement should allow the final peer-reviewed manuscript to be deposited in <u>PubMed Central</u> immediately upon acceptance for publication and made available to the public in <u>PubMed Central</u> no later than 12 months after journal publication.

To inform the journal that the article is subject to the <u>NIH Public Access Policy</u>, an author should <u>cite</u> the <u>NIH grant(s)</u> in the acknowledgement section of the article as indicated in the Notice of Award. NIGMS provides additional <u>guidance</u> on acknowledging a grant. Below is language to be used in the publication acknowledgements:

Manuscripts using BUILD consortium-wide data should use the following language:

The authors prepared this manuscript on behalf of the Diversity Program Consortium. A complete listing of individuals who contributed to this work is maintained on the Diversity Program

Consortium webpage. Work reported in this publication was supported by the Office of The Director, National Institutes of Health Common Fund and Office of Scientific Workforce Diversity awards UL1GM118979, UL1GM118976, UL1GM118973, UL1GM118964, UL1GM118985, UL1GM118991, UL1GM118982, UL1GM118988, UL1GM118970, UL1GM118967, and U54GM119024 administered by the National Institute of General Medical Sciences. The work is solely the responsibility of the authors and does not necessarily represent the official view of the National Institutes of Health.

Manuscripts using NRMN Phase I, CEC follow-up data should use the following language:

Work reported in this publication was supported by the Office of The Director, National Institutes of Health Common Fund and Office of Scientific Workforce Diversity awards U54GM119023 and U54GM119024 administered by the National Institute of General Medical Sciences. The work is solely the responsibility of the authors and does not necessarily represent the official view of the National Institutes of Health.

Manuscripts using site-level data for a BUILD site with no CEC collected data should use the following language:

Work reported in this publication was supported by the Office of the Director, National Institutes of Health Common Fund and Office of Scientific Workforce Diversity three linked awards RL5GM#####1, TL4GM#####1, and UL1GM#####1 administered by the National Institute of General Medical Sciences. The work is solely the responsibility of the authors and does not necessarily represent the official view of the National Institutes of Health.

Manuscripts using sub-consortium data should use the following language:

Work reported in this publication was supported by the Office of The Director, National Institutes of Health Common Fund and Office of Scientific Workforce Diversity awards [insert grants numbers here with the appropriate format²] administered by the National Institute of General Medical Sciences. The work is solely the responsibility of the authors and does not necessarily represent the official view of the National Institutes of Health.

Manuscripts using site-level data with a single award should use the following language with the relevant grant number:

Work reported in this publication was supported by the Office of the Director, National Institutes of Health Common Fund and Office of Scientific Workforce Diversity award xxxGMxxxxxx³ administered by the National Institute of General Medical Sciences. The work is solely the responsibility of the authors and does not necessarily represent the official view of the National Institutes of Health.

Manuscripts using CEC Phase II support or CEC co-authors should also use the following language with the relevant grant number:

Work reported in this publication was supported by NIH Grant U54GM119024 as well as the following NIH offices, centers and institutes: Office Of The Director (Common Fund and Office of Scientific Workforce Diversity), Fogarty International Center, NIH Office of Research

¹ CSULB: 118979, CSUN: 118976, MSU: 118973, PSU: 118964, SFSU: 118985, UAF: 118991, UDM: 118982, UMBC: 118988, UTEP: 118970, XULA: 118967

² If the collaboration required data gathered by the CEC, include the CEC grant number: U54GM119024 ³ CEC: U54GM119024; NRMN Phase I: U54GM119023; NRMN Coordination Center: U24GM132176; NRMN Resource Center: U24GM132217; NMRN U01's: GM132133, GM132219, GM132366, GM132374, GM132375, GM132771, GM132367, GM132174, GM132175, GM132372, GM132769

Infrastructure Programs, NICHD, NCATS, NIGMS, NCI, NIDA, NCCIH, NLM, NINDS, NIEHS, NIDCR, NIDDK, NIAMS, NINR, NIDCD, NHGRI, NIMH, NEI, NHLBI, NIAID, NIMHD, NIBIB, NIA, and NIAAA. The work is solely the responsibility of the authors and does not necessarily represent the official view of the National Institutes of Health.

Appendix 1: Preapproval Proposal Form for Products Using Consortium-Wide Data

TITLE OR TOPIC AREA

TITLE OR TOPIC AREA
LEAD AUTHOR INFORMATION Name (Last Name, First Name): Email Address: Telephone:
TYPE OF PROPOSAL AND DATA
Indicate the type of product requiring consortium-wide data
☐ Manuscript
Dissertation
☐ Presentation/Poster
☐ Publicly Available Data Brief
☐ Preliminary Results Section in a Grant Application
Indicate whether the process should be expedited
□ No
Yes – indicate the deadline
Select the most appropriate description of the data request
☐ Consortium-wide – must submit a proposal
☐ Sub-consortium ⁴
Select the most appropriate description of the type of data request
Focused, hypothesis-driven (preferred with a faster turnaround time for data requests)
☐ Exploratory, open-ended (requires extensive wait time for data requests)
CONFLICTS OF INTEREST
Do any of the proposed authors have conflicts of interest (i.e., is an author in a position to
derive personal benefit from the outcomes of the research)?
Yes - if yes, indicate the nature of the conflict

Narrative for Sub-Consortium Data Requests

- Authors must provide a brief summary of the topic and specific questions underlying the data request.
- Authors should note how the project is not a consortium-wide study.
- Indicate the consortium <u>data</u> required for the analysis (e.g., survey questions, demographics). Applicants should consult the <u>Hallmarks of Success mapping document</u> to identify the data sources associated with each <u>Hallmark of Success</u>.
- Sub-consortium data requests must provide a letter of consent from all involved contact Principal Investigators.

⁴ Research and/or pre-existing or proposed collaborations on consortium-related topics that include two or more DPC awardees but are not consortium-wide collaborations.

Narrative for Consortium-Wide Publications or Products

I. BACKGROUND AND SIGNIFICANCE

- Describe the gap in knowledge this research will address. Applicants must provide a summary of the current body of knowledge leading up to the proposed research.
- Indicate the target audience.
- Describe the potential impact of the analysis.

II. DESCRIPTION

- Provide the specific hypothesis and/or research questions.
- Indicate whether the hypothesis/research question is grounded in a conceptual/theoretical framework.
- List the Hallmarks of Success associated with this topic.
- Describe the training, mentoring or capacity-building intervention(s) being researched.
- Indicate who is being influenced by the intervention(s).
- Describe the baseline or comparator group(s).

III. DATA AND ANALYSIS PLAN

- Indicate the <u>data</u> required for the analysis (e.g., survey questions, demographics using the chart below). Applicants should consult the <u>Hallmarks of Success mapping document</u> to identify the data sources associated with each <u>Hallmark of Success</u>.
- Provide a brief statistical analysis plan and methods (authors are encouraged to use the DPC Data Methods Guidelines). Plans may include, but not be limited to Multiple Linear Regression, Hierarchical Linear Modeling, Binomial Logistic Regression, Ordinal Logistic Regression, Multinomial Logistic Regression, Sequential Logistic Regression, Structural Equation Modeling, and Difference in Difference Estimation.
- Explain how the data analysis will address the hypothesis and/or research questions.

IV. TEAM MEMBERS

- Provide a list with the name, role(s), and relevant expertise for each member of the team. The
 consortium-wide analyses are complex in nature and will require expertise across a range of
 disciplines. The DPC encourages a collaborative effort including program administrators,
 educators, psychologists, sociologists, biostatisticians, and/or economists.
- Explain how the team will bring complementary and integrated expertise to ensure rigor, validity, generalizability, and integration of the findings.

V. PUBLICATION TIMELINE & INTENDED JOURNAL

- Provide a timeline with an estimated date for submission or public release.
- Please indicate the journal you plan to submit this manuscript to, and any related publication costs. If there are publication costs, please provide a justification for the costs and indicate which site(s) will be responsible for payment.

CWEP Data	Select the Dataset(s) of Interest	Constructs/Variables
Reference File (source for		
participation activity flags)		
HERI TFS 2015		
HERI YFCY 2016		
HERI TFS 2016		
CEC Interim Survey 2016		
HERI TFS 2017		
HERI CSS 2017		
HERI FAC 2017		
CEC SAFS 2017		
HERI TFS 2018		
CEC SAFS 2018		
CEC FAFS 2018		
HERI CSS 2018		
BUILD Faculty Mentor-		
Nominated Mentee Survey		
2018		
*HERI TFS 2018		
*CEC SAFS 2019		
*HERI CSS 2019		
*HERI FAFS 2019		
*BUILD Faculty Mentor-		
Nominated Mentee Survey		
2019		
*HERI TFS 2019		
*CEC SAFS 2020		
*HERI CSS 2020		
*HERI FAC 2020		
*CEC SAFS 2021		
*HERI CSS 2021		
*CEC FAFS 2021		
*BUILD Faculty Mentor-		
Nominated Mentee Survey		
2021		
*CEC SAFS 2022		
*HERI CSS 2022		
*CEC FAFS 2022		
*BUILD Faculty Mentor-		
Nominated Mentee Survey		
2022		
*CEC SAFS 2023		
*HERI CSS 2023		
*HERI FAC 2023		
*Indicates that data are n	at viet evicilable. Can timeline for fut	

^{*}Indicates that data are not yet available. See timeline for future data release.

Appendix 2: Reviewer's Form for Preapproval Proposals

I. BACKGROUND AND SIGNIFICANCE

- Is there overlap with an existing approved consortium-wide publication or product? Y/N, unable to answer if yes, explain.
- Does the proposal describe the gap in knowledge that the proposed research will address? Y/N, unable to answer if no, explain.
- Does the proposal include a comprehensive summary of the current body of knowledge leading up to the proposed research? Y/N, unable to answer if no, explain.
- Is the target audience for the analysis within the biomedical research workforce? Y/N, unable to answer if no, explain.
- Is the analysis likely to inform and have a significant impact on developing the biomedical research workforce? Y/N, unable to answer if no, explain.

II. DESCRIPTION

- Are the specific hypothesis(es) and/or research question(s) rigorous? Y/N if no, explain.
- Will the specific hypothesis(s) and/or research question(s) address the gap identified in the literature? Y/N, unable to answer if no, explain.
- Are the hypotheses/research questions grounded in a conceptual/theoretical framework? Y/N if no, explain.
- Do the stated hypothesis(es) and/or research question(s) align with the <u>Hallmarks of Success</u> listed in the proposal? Y/N if no, explain.
- Does the selected intervention(s) align with the proposed hypothesis and/or research questions? Y/N if no, explain.
- Does the proposal clearly define the population included in the analysis? Y/N if no, explain.
- Does the proposal include an appropriate baseline or comparator group(s)? Y/N if no, explain.

III. DATA AND ANALYSIS PLAN

- Is the data being requested appropriate for the analysis as described? Y/N, unable to answer if no, explain.
- Does the proposal clearly describe the statistical analysis plan and methods? Y/N, unable to answer if no, explain.
- Does the proposal adequately explain how the data and method of analysis will address the hypothesis(es) and/or research question(s)? Y/N, unable to answer if no, explain.

IV. WRITING GROUP MEMBERS

- Does the writing group have the interdisciplinary expertise necessary to conduct the proposed analysis? Y/N if no, explain.
- Does the proposal describe the responsibilities and time commitment requirements for each group member? Y/N if no, explain.

V. PUBLICATION TIMELINE & INTENDED JOURNAL

• Is the proposed publication timeline realistic? Y/N – if no, explain.

- Is the proposed journal an appropriate publication venue? Y/N if no, explain.
- Have the authors provided a justification for any costs associated with publication, as well as denoting responsibility for these charges? Y/N if no, explain.

VI. ADDITIONAL NOTES OR COMMENTS

Please add any additional notes or comments on the manuscript proposal.

VII. RECOMMENDATION

	Approval of the proposal to proceed as submitted.
	Provisional approval, pending revisions requiring re-review by the PPsC.
	Conflicts with a previously approved proposal, requires consultation with PPsC.
П	Non-acceptance of the proposal, but with recommendations for revisions.

Appendix 3: Final Submission Checklist for Products using Consortium-Wide Data

TITLE	
TYPE OF	PRODUCT (MUST BE ATTACHED) Manuscript Dissertation Presentation/Poster Publicly Available Data Brief Preliminary Results Section in Grant Proposal
	NCE TO ORIGINAL PLAN ne final product align with the original proposal? Yes No - if no, indicate the nature of the difference in an attached document
Does the manusco	TEL APPROVAL ne submission include approval from all Principal Investigators named in the final cript or product? Yes No Not Applicable
AUTHOR: Does th	SHIP ne final product follow the guidelines for authorship? Yes No
Do any	of the proposed authors have conflicts of interest (i.e., is an author in a position to personal benefit from the outcomes of the research)? No Yes - if yes, has the author(s) disclosed the conflict?
Does th	LEDGEMENTS ne final product follow the guidelines for acknowledging the DPC, NIH, and the ted grant awards? Yes No

PUBLICATIONS ONLY

Indicate the journal to which the authors plan to submit this manuscript. Have there been any
changes to the publication cost sharing described in the original proposal?
☐ Yes
□ No

Appendix 4: Reviewer's Form for Final Submissions using Consortium-Wide Data

ADHERENCE TO ORIGINAL PLAN	
Does the final product align with the original prop	oosal?
☐ Yes	
☐ No - if no, indicate the nature of the differ	rence in an attached document
SITE-LEVEL APPROVAL	
Does the submission include approval from all Pr	incipal Investigators of the sites/programs
named in the manuscript or product?	
☐ Yes	
□ No	
☐ Not Applicable	
AUTHORSHIP	
Does the final product follow the guidelines for an	athorship?
☐ Yes	
□ No	
CONFLICTS OF INTEREST	
Do any of the proposed authors have conflicts of i	
derive personal benefit from the outcomes of the	research)?
□ No	
Yes - if yes, has the author(s) disclosed th	e conflict?
ACKNOWLEDGEMENTS	
Does the final product follow the guidelines for ac	knowledging the DPC, NIH, and the
associated grant awards?	
☐ Yes	
□ No	

ADDITIONAL COMMENTS

Appendix 5: Submitting Non-CWEP Publication Products to the PPsC for Archiving

Although authors are not required to submit non-CWEP publication products or sub-consortium products to the PPsC, they are strongly encouraged to do so. This facilitates maintenance of an up-to-date catalogue of publications that cite DPC grants and aids in identifying opportunities for collaborations.

T	ľ	П	Æ

TY	PE OF PUBLICATION
	Site-Level Data
	Sub-Consortium Products
LE.	AD AUTHOR INFORMATION
Na	me (Last Name, First Name):
En	nail Address:
Te	lephone:
DF	PC Site Affiliation:

CO-AUTHOR(S) INFORMATION

Name (Last Name, First Name): Email Address: Telephone: DPC Site Affiliation:

JOURNAL INFORMATION

Journal Name: Publication Date: DOI: PubMed ID: Article Hyperlink:

Appendix 6: Schematic Diagram of PPsC Process

