

BACPAC Data Access and Publications Policy

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The purpose of this document is to establish a framework that facilitates access to the data stored on the BACPAC Data Portal and oversees submission of manuscripts, meeting abstracts, and presentations. The Data Access and Publications Committee (DAPC) oversees the activities set out herein on behalf of the BACPAC Steering Committee (SC), and reports to it. Changes to the policy described herein, which are expected from time to time, must be approved by the SC. The policy applies to a proposed publication if the published results are the product of research that was funded, in part or whole, by an NIH BACPAC prime or sub-award, or if the publication uses data stored on the BACPAC Portal.

Contents

1. Scope	2
2. Membership	2
3. Data requests	2
3A External Requests	2
3B Internal Requests	2
3C All Requests	3
4. Publication proposals	3
4A Proposals requiring approval by the DAPC	3
4B Proposals requiring DAPC approval and authorship selection	3
4C Proposals not requiring approval by the DAPC	4
4D Abstracts and presentations	4
5. Review process for data requests and manuscript proposals	4
5A Data Request Review Options	5
5B Publication Proposals Review Options	5
5B.1 Authorship policy for manuscripts requiring authorship intervention	6
5B.2 Publication Proposals that Do Not Require DAPC Review	6
6. Post-Review Actions and Requirements	6
6A Notification of acceptance of the manuscripts for publication	6
6B Notification of publication	7
7. Acknowledgements	7
8. NIH Public Access Policy	7
9. Archives	8
Appendix A: Data Access and Publications Request Form	9

1. Scope

- To assist the Data Integration, Algorithm Development and Operations Management Center (DAC) with tracking, review and approval of data access requests for data stored on the BACPAC Data Portal.
- To assist with tracking, review and approval of manuscript proposals.
- To track abstracts and scientific presentations.
- To maintain an up-to-date list of all publications, presentations, abstracts and data requests.

2. Membership

The Data Access and Publications Committee (DAPC) is made up of one representative from each of the BACPAC funded units: Mechanistic Research Centers, Technology Research Sites, Clinical Trial sites, and the DAC, and an NIH representative.

3. Data requests

3A. External Requests

External collaborators (investigators outside of the BACPAC consortium) that have been approved by the BACPAC Executive Committee (EC) may request access to data on the BACPAC Data Portal for submission of data and/or analyses to be conducted within the platform. External collaborators may request access to the BACPAC Data Portal as a BACPAC *Affiliate*. Affiliate status requires the endorsement of an NIH representative or a BACPAC member institution PI. The endorsement does not convey any formal responsibility to the endorsing party. These external collaborators may request access to their data (if applicable) and/or any other datasets that they intend to use in combined analysis(es)/research activities. Prior to accessing the data portal, external collaborators (regardless of whether they contribute data) must establish a data use agreement with the DAC per UNC institutional requirements.

IRB approval does not need to be provided by external collaborators prior to DAPC review. Once the DAPC has approved a request to use the BACPAC Data Portal, the requestor will be required to provide IRB approval/determination for their proposed research activities to the DAC in order to be granted access to the BACPAC Data Portal. IRB approval is not required for the submission of data; IRB approval is only required for access to datasets not submitted by the requestor and/or access for research analysis purposes. External collaborators may receive IRB approval/determination from either their local IRB or IRB of record (i.e., if they are involved in a research study that has a single IRB, such as an ancillary project).

3B. Internal Requests

Investigators/study staff at BACPAC member institutions and affiliated with BACPAC research projects must 1) be listed on the IRB Reliance Agreement with Advarra for BACPAC Data Portal

Protocol and 2) have a Data Use Agreement established between the BACPAC investigators'/study staff's institution and the DAC in order to be approved for access to the BACPAC Data Portal.

3C. All Requests

Unless prohibited by the data contributor, basic summary level data (e.g., number of patients summarized by race) may be made available without IRB approval for specific research activities.

Requests to access data are managed through the interactive BACPAC Microsoft Teams channel or other secure method external to Teams as determined by the DAPC. The request form is included as Appendix A.

4. Publication proposals

Publication proposals fall under one of two categories: proposals that require approval by the DAPC and proposals that are reported to the DAPC but do not require approval. All manuscript proposals are tracked using the Data Access and Publications Request Form via MS Teams, and the interactive BACPAC Manuscript Tracking System (MTS). Proposals requiring DAPC review and approval must be submitted to the DAPC via the Request Form before the writing process has begun. Proposals that do not require DAPC review are encouraged to be reported as soon as possible but are not required to be submitted via the request form and entered into the BACPAC MTS until the manuscript is submitted for publication.

The DAPC reserves the right to request a draft of BACPAC manuscripts prior to submission for publication. Proposing authors may also request the DAPC review a draft of their manuscript. The DAPC will not review drafts of manuscripts unless specifically requested by DAPC members or proposing authors.

4A Proposals requiring approval by the DAPC

Manuscript proposals requiring DAPC approval are generally those that emanate from within the DAC structure or those that propose to use the BACPAC Data Portal data. Examples include proposals for manuscripts:

- originating at the DAC, e.g. a protocol paper
- to be written by a BACPAC working group, e.g. a paper on the design of the theoretical model of cLBP
- by a BACPAC project that requests another BACPAC project's data when there is no existing collaboration with that project
- by a non-BACPAC investigator using the BACPAC Portal data
- analyzing data that has previously been accessed

4B Proposals requiring DAPC approval and authorship selection

Manuscript proposals requiring DAPC approval and authorship selection meet the criteria as described in section 4A, and also meet at least one of the criteria below:

- report on key BACPAC findings.
- report on the design of the BEST trial
- report of the primary data analysis of the BEST trial
- are determined to require authorship selection and/or final draft review based on DAPC discretion and/or request of proposal authors

4C Proposals not requiring approval by the DAPC

Manuscript proposals that do not require review are those that do not meet the criteria listed in sections 4A or 4B. Examples include proposals for papers

- by any site (Mechanistic Research Center, Technology Site, Phase 2 Clinical Trial) reporting on their own data (regardless whether the site's data are being accessed from the BACPAC Portal or locally);
- that propose analyses funded through BACPAC grants without data or using data produced outside of BACPAC (e.g. a statistical methodology paper by a statistician at one of the Technology Sites);
- by two or more BACPAC sites who agree to work together on a joint paper that might or might not use joint data but does not use data from other sites.

4D Abstracts and presentations

As much as is feasible, all published abstracts and the titles, location, and dates of major presentations should be sent to the DAPC so that they may be posted to the BACPAC website and added to the BACPAC list of publications and presentations. All abstracts and presentations are required to reference the BACPAC research program (see Appendix B).

Presentations (oral and poster) and abstracts of BACPAC findings associated manuscripts described in 4B require full review prior to submission.

5. Review process for data requests and manuscript proposals

Each unique request for data access and/or manuscript proposal is submitted through MS Teams or other secure platform as determined by the DAC. Forms are checked for completeness, and, if incomplete, the requester is notified. If additional data are needed for an already approved request, an amendment to the original request must be submitted for approval.

Data requests and manuscript proposal requiring DAPC review will be reviewed by up to two reviewers assigned by the DAPC. Requests and manuscript proposals are determined by majority vote among remaining DAPC members in attendance during a regularly scheduled bi-weekly meeting. Therefore, the review process will take between 1 and 4 weeks depending upon the committee meeting schedule and workload. In cases where the DAPC cannot vote on a proposal during a meeting (e.g., quorum of at least seven members is not met or the proposal has an urgent timeline), the DAPC will vote on proposals via email. Requests will be (1) approved, (2) approved with revisions, (3) rejected, or (4) returned due to incompleteness/ambiguity. For data requests, the representative from the requesting unit will be excluded from voting on the request. For data requests emanating from investigators external to BACPAC, the DAPC may require a

representative from the external organization to attend a DAPC meeting to provide additional data or rationale for the request.

If a decision cannot be made, the DAPC will consult the EC. Should it become necessary to revise a proposal, the proposal author should submit a new proposal to the DAPC that highlights the changes in the text. The revised proposal is then reviewed as described above. Once the proposal has been approved, the DAC enters the proposal information into the MTS, where the manuscript is tracked through publication.

5A Data Request Review Options

As determined by the DAC and DAPC, some data may be deemed minimally restricted, for example, data pre-approved for consortium wide use. Datasets designated as minimally restricted will be made available for access on the portal after administrative processing; access to these data will not require full DAPC review. Completed requests follow the review processes below.

Data access requests for a BACPAC project to deposit or access their own data on the BACPAC Data Portal or data requests for non-publication purposes will not require review by the DAPC. These requests will require only administrative review by the DAC DAPC representative and will be stored on MS Teams.

Requests from external collaborator will require an initial assessment by the DAC DAPC representative to evaluate the BACPAC Data Portal resource requirements associated with the collaborator's proposed research activities. If the proposed research activity is viewed as requiring too many resources (e.g., excessive computing costs), the request will not be allowed to proceed. Otherwise, the request will follow standard DAPC review for data access requests.

See Section 5B regarding data requests for publication purposes.

5B Publication Proposals Review Options

Manuscript proposals requiring DAPC review and approval as described in sections 4A and 4B must be submitted into the BACPAC MTS via the Request Form on Teams before the writing process has begun. As a part of the review process, the DAPC informs sites whose data are being requested. This allows the sites to be involved in the paper writing process (if interested) and be a co-author. Reviewers will review the proposal for overlap with existing BACPAC manuscript proposals and BACPAC publications. Publication proposals may be rejected if there is overlap with existing papers. Units should check the list of existing papers/proposals to determine if there is overlap prior to submitting a request. If the DAPC deems that there is significant overlap, they will inform the requesting unit and encourage them to collaborate with the units with whom there is overlap. The DAPC will evaluate the scientific merit of the proposal, if feasible, and will provide comments.

For publication proposals, the reviewers should evaluate if authorship intervention by the DAPC is needed based on section 4B (or for any other reasons). The DAPC decides if the authorship

selection is needed by the majority vote. Requesting units are notified of the review outcome and provided DAPC members' feedback at the end of the review period. If authorship intervention is not required, it may still be recommended by the reviewer, or requested by the writing group.

5B.1 Authorship policy for manuscripts requiring authorship intervention

Under the authorship policy set by the DAPC, authors are expected to draft content, revise work critically for important intellectual content, or play a key role in the acquisition, analysis, or interpretation of data for the work, but individual units may rely on their own internal criteria when nominating individuals for authorship or acknowledgement.

Each manuscript proposal requiring the DAPC review should list proposed writing group members, typically no more than six, and proposed lead authors. The list of co-authors typically consists of at most two investigators from each of the BACPAC units involved in the corresponding project and the NIH Project Officer(s) or Project Scientist(s) as appropriate. Representation from some units may be increased if greater than two individuals meet the DAPC requirement for authorship, if appropriate. Co-authors are nominated by the BACPAC unit involved in the project. Note that the lead authors do not count against the two-co-author limit. The writing group is typically a subset of the co-author list. The DAPC facilitates the process of creating the list of co-authors, reviews the co-author list, and recommends additions or changes when appropriate.

Investigators participating in the study but not in the writing of the paper may be listed in the acknowledgements section.

These guidelines may be modified as needed for papers relating to the BEST Trial.

5B.2 Publication Proposals that Do Not Require DAPC Review

Proposals that do not require DAPC review and approval should be submitted to the DAPC at the same time as they are submitted to the journal so that these manuscripts can be tracked using the interactive BACPAC Manuscript Tracking System (MTS). Authors are welcome to submit proposals sooner.

6. Post-Review Actions and Requirements

After approval by the DAPC, proposals are posted on the BACPAC Microsoft Teams channel or other secure method as determined by the DAPC. Any investigator wishing to join the writing group should contact the first author, who will be responsible for updating the MTS.

6A Notification of acceptance of the manuscripts for publication

Investigators should notify the DAPC when manuscripts are accepted and provide the expected publication date. Final manuscripts should be submitted to the DAPC and the journal simultaneously.

The DAPC will be responsible for ensuring grantees and other partners notify HEAL Communications, alongside their program officers, of any scientific publication or manuscript immediately upon acceptance for publication by a journal. Notification should be made by sending an email to HEAL Initiative at HEALquestion@od.nih.gov and to the assigned program officer.

6B Notification of publication

Investigators should notify the DAPC when manuscripts are published. Published versions of the manuscripts need to be provided to DAPC.

7. Acknowledgements

All papers, abstracts, and presentations (oral and poster) should include the acknowledgment: *The Back Pain Consortium (BACPAC) Research Program is administered by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).*

If data from a certain Mechanistic Research Center, Technology Research Site or Phase 2 Clinical Trial are included, papers, abstracts and presentations (oral and poster) should include the corresponding grant number in the acknowledgment (see Appendix B).

BACPAC researchers who publish using data collected by other BACPAC researchers will be required to cite, at minimum, the protocol paper for the study through which the data were collected.

Additionally, the NIH grants policy statement outlines requirements for acknowledging Federal funding in the following products when describing projects or programs funded in whole or in part with NIH funds:

- research publications
- press releases and other public statements
- other publications or documents about research that is funded by NIH
- requests for proposals and bid invitations
- and other documents describing projects or programs funded in whole or in part with Federal money

should include the following statements:

Statement of support

This research was supported by the National Institutes of Health through the NIH HEAL Initiative under award number [specific NIH grant number(s) in this format: R01GM987654].

Grantees should also include a disclaimer that says:

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or its NIH HEAL Initiative.

8. NIH Public Access Policy

The NIH Public Access Policy states that all NIH-funded studies must submit copies of their manuscripts to the digital archive PubMed Central (PMC) once accepted for publication to a peer-reviewed journal. Authors should review the journal's copyright agreement before signing and determine if they allow for submission to PMC without embargo. If not, it is the author's responsibility to negotiate with the journal to make sure this is allowable. Once accepted for

publication, the manuscript should be submitted to the NIH Manuscript Submission system at <http://www.nihms.nih.gov>. The manuscript will be assigned a PMCID. The Coordinating Center should be notified of the PMCID as soon as it is available. For more information on the NIH Public Access Policy, please visit <http://publicaccess.nih.gov>.

9. Archives

The DAC maintains an electronic archive of all BACPAC publications. Electronic copies of the final version of all papers and abstracts are posted on the BACPAC website.

Appendix A: Data Access and Publications Request Form

Note: The data access and publications request form will be programmed using Qualtrics or fillable form. Skips will be incorporated in the programming so that users are prompted to answer only questions applicable to the current request.

1. Please enter your full name.
2. Please select your affiliated site and PI from the following list. [PI will be notified of this request]
3. What type of request are you making?
 - a. New request to access another unit's data for non-publication purposes (**answer questions 4-11, 19**)
 - b. New request to access another unit's data for publication purposes (**answer 4-19**)
 - c. New publication proposal only (access to data on the BACPAC Data Portal is not being requested) (**answer questions 12-19**)
 - d. New request to access my own unit's data for analysis on the BACPAC Data Portal for non-publication purposes (**answer 5, 6, 9-11, 19**)
 - e. New request to access my own unit's data for analysis on the BACPAC Data Portal for publication purposes (**answer 5, 6, 9, 11, 19**)
 - f. Modification to a previous request (e.g. a new publication request on data accessed previously, or a request for access to additional data for a previously reported research question) (**answer 20, TBD**)
4. (a, b) Describe any discussions your unit has had with the data-owning unit regarding this proposal. Please indicate the willingness of the data-owning unit to collaborate on this proposal.

Note: If applicable and appropriate, discussions regarding collaboration are encouraged to begin prior to the data access or publication request.
5. (a, b, d, e) Please list the dataset(s) to which you are requesting access.
6. (a, b, d, e) Please list all those who will need access to the data and analytic tools on the BACPAC Data Portal.
 - a. Name
 - b. Affiliated Site and PI
 - c. MS Teams user account email
 - d. Role (e.g. statistician, investigator)
7. (a, b) What research question or hypothesis do you intend to address using this data?
8. (a, b) To the best of your knowledge, is this research question unique within the consortium? Explain.
9. (a, b, d, e) Will your analysis of the requested data require high performance computing on the portal?

10. (a, b, d) You have indicated you are requesting data only without plans to publish. Do you plan to publish on the data in the future?
11. (a, b, d, e) Does this research effort rely on BACPAC Pilot and Ancillary Study funding?
Note: Receipt of funding does not guarantee approval of data access by this committee.
 - a. If yes, has this funding been secured?
12. (b, c) Please list the lead author.
13. (b, c) Please list the co-authors.
14. (b, c) Please provide a synopsis of proposed manuscript including hypotheses/objectives, study design and inclusion/exclusion criteria.
15. (b, c) Please provide a brief overview of statistical analysis plan.
16. (b, c) What is the proposed timeline of analysis?
17. (b, c) Is this publication request based on exploratory analyses conducted on this data previously?
18. (b, c) What is the intended journal for this publication?
19. (a, b, c, d, e) Please provide any other information that might be helpful to the Data Access and Publications Committee.
20. (e) Select the request to be modified.

Appendix B: Grant Numbers

Grant Number	Proposal Title	Location	PI	Unit
1UH2AR076731-01	Development, Evaluation and Translation of Robotic Apparel for Alleviating Low Back Pain	HARVARD UNIVERSITY	WALSH, CONOR	TECH
1UH2AR076736-01	Focused Ultrasound Neuromodulation of Dorsal Root Ganglion for Noninvasive Mitigation of Low Back Pain	UNIVERSITY OF UTAH	RIEKE, VIOLA	TECH
1U19AR076725-01	HEALing LB3P: Profiling Biomechanical, Biological and Behavioral phenotypes	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	SOWA, GWENDOLYN	MRC
1UH2AR076741-01	Imaging Epigenetic Dysregulation in Patients with Low Back Pain	MASSACHUSETTS GENERAL HOSPITAL	WEY, HSIAO-YING	TECH
1UH2AR076719-01	Novel imaging of endplate biomarkers in chronic low back pain	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	FIELDS, AARON	TECH
1UG3AR076568-01	Proof of concept study to treat negative affect in chronic low back pain	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	WASAN, AJAY	Phase 2
1UG3AR076573-01	Randomized-controlled trial of virtual reality for chronic low back pain to improve patient-reported outcomes and physical activity	CEDARS-SINAI MEDICAL CENTER	SPIEGEL, BRENNAN	Phase 2
1UH2AR076724-01	Technology Research Site for Advanced, Faster Quantitative Imaging for BACPAC	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	MAJUMDAR, SHARMILA	TECH
1UH2AR076729-01	The Spine Phenome Project: Enabling Technology for Personalized Medicine	OHIO STATE UNIVERSITY	MARRAS, WILLIAM	TECH
1U19AR076737-01	UCSF Core Center for Patient-centric Mechanistic Phenotyping in Chronic Low Back Pain	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	LOTZ, JEFFREY	MRC

1U19AR076734-01	University of Michigan BACPAC Mechanistic Research Center	UNIVERSITY OF MICHIGAN AT ANN ARBOR	CLAUW, DANIEL	MRC
1UH2AR076723-01	Wearable nanocomposite sensor system for diagnosing mechanical sources of low back pain and guiding rehabilitation	BRIGHAM YOUNG UNIVERSITY	BOWDEN, ANTON	TECH
1U24 AR076730-01	BACPAC DAC	UNC AT CHAPEL HILL	PSIODA, MATTHEW	DAC
1U24NS113844-01	EPPIC-NET DCC	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	PETKOVA, EVA; TROXEL, ANDREA	DCC