

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.

I. Scope

1. 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.
2. To assist with tracking, review and approval of manuscript proposals.
3. To track abstracts and scientific presentations.
4. To maintain an up-to-date list of all publications, presentations, abstracts and data requests.

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.

Data requests

A. External Requests

External contributors (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 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 contributors may request access to their data and any other datasets that they intend to use in combined analysis(es)/research activities with their dataset(s). Prior to accessing the data portal to submit their data, external collaborators must establish a data use agreement with the DAC.

IRB approval does not need to be provided by external contributors 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 contributors 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).

B. 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.

C. 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.

Publication proposals

Publication proposals fall under one of two categories: proposals that require approval by the DAPC (Type 1 proposals) and proposals that are reported to the DAPC but do not require approval (Type 2 proposals). All manuscript proposals are tracked using the interactive BACPAC Manuscript Tracking System (MTS). Type 1 proposals must be entered into the BACPAC MTS before the writing process has begun and require review and approval by the DAPC. Type 2 proposals must be entered into the BACPAC MTS at the same time the manuscript is submitted for publication and do not require review.

Proposals requiring approval by the DAPC (Type 1 proposals)

Manuscript proposals requiring review, Type 1 proposals, 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;
- on data that has previously been accessed.

Type 1 manuscripts that are network-wide and/or describe key BACPAC findings are categorized as *primary manuscripts*. An example of a *primary manuscript* is a paper that reports results of any BACPAC-wide clinical trial. Primary manuscripts are subject to additional rules such as authorship rules.

Proposals not requiring approval by the DAPC (Type 2 proposals)

Manuscript proposals that do not require review, Type 2 proposals, are generally those that do not originate at the DAC or a BACPAC working group or those that do not rely on the BACPAC Data Portal data (with the exception of proposals requesting access to the unit's own data for analysis on the BACPAC Data Portal). 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.

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 with primary manuscripts require full review prior to submission. The approval process for presentations of findings associated with primary manuscripts is the same as that for Type 1 manuscript proposals.

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.

Requests from external contributors will require an initial assessment by the DAC DAPC representative to evaluate the BACPAC Data Portal resource requirements associated with then contributor'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.

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.

The representative from the proposing unit will be excluded from voting on the request. Requests will be approved, approved with revisions, or rejected by majority vote among remaining DAPC members in attendance during a regularly scheduled bi-weekly meeting. In no case will a vote take place with fewer than seven voting members. For 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.

Data Requests to Deposit or Access a site's own Data and Data Requests for Non-Publication Purposes

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. DAPC members will be alerted to such requests via email.

Publication Proposals and Data Requests for Publication Purposes

For publication requests, the designation of Type 1 and Type 2 is made by the proposer and is confirmed by the DAC staff in consultation with the DAPC committee chair or representative if needed. Units requesting the use of data from other units should plan to collaborate with those units.

Type 1 Publication Proposals

Type I proposals must be submitted into the BACPAC MTS before the writing process has begun. Type 1 requests are reviewed by at least two reviewers assigned by the DAPC. 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. The DAPC will evaluate the scientific merit of the proposal, and will provide comments. If extensive overlap exists, the DAPC will notify the requester and may recommend collaboration.

Proposals are approved, approved with revisions, or rejected by majority vote among non-conflicted DAPC members during a regularly scheduled bi-weekly meeting as outlined above, therefore the review process will take between 1 and 4 weeks depending upon the committee meeting schedule and workload. Requesting units are notified of the review outcome and provided DAPC members' feedback at the end of the review period.

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 Type 1 request has been approved, the DAC enters the proposal information into the MTS, where the manuscript is tracked through publication.

The final draft of each primary manuscript is reviewed by the DAPC to provide comments and to finalize the list of authors according to the authorship policy prior to submission to a journal (see next section).

Authorship policy for primary manuscripts

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 primary manuscript proposal 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 for primary manuscripts, 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.

Type 2 Publication Proposals

Type 2 manuscript proposals 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).

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. The DAC is responsible for keeping the public-facing website up to date.

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.

Notification of publication

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

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.

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>.

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
1U24AR076730-01	BACPAC DAC	UNC AT CHAPEL HILL	LAVANGE, LISA	DAC
1U24NS113844-01	EPPIC-NET DCC	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	PETKOVA, EVA; TROXEL, ANDREA	DCC