

## **Dataset Access and Publication Policies**

(Draft Guidelines as of 06/03/2016)

### ***Purpose of Guidelines***

The intent of these policies is to facilitate the use of the PHAR data, to encourage collaboration among PHAR investigators, as well as to provide a mechanism for tracking intended analyses, presentations, and publications related to and resulting from PHAR data. These guidelines are to ensure appropriate use of the PHAR data, timely completion of projects, and adherence to timelines and principles of authorship.

### ***Administrative Structure***

The chairperson for the PHAR Steering Committee will appoint a Publications and Presentations (P&P) Committee. This Committee shall consist of at least one representative from the:

- Coordinating Center (CC)
- Pulmonary Hypertension Association (PHA) medical leadership
- PHCC sites

The P&P Committee will provide scientific and analytic review of concept proposals utilizing PHAR data.

All communications to the P&P Committee should be sent to the P&P Program Coordinator. The P&P Coordinator will be responsible for ensuring that the committee receives all necessary materials and communication for concept proposals, conference abstract presentations, and manuscripts/pen drafts.

### ***Investigators Eligible to Submit Proposals***

The following investigators are eligible to submit concept proposals entailing use of the PHAR data:

- a. PHCC Directors who have contributed data to the PHAR.
- b. Members of the contributing PHCC Director's team, including co-investigators, local colleagues (e.g. nurses and study coordinators), and/or other approved investigators (i.e. students, postdocs). Approval from a sponsoring PHCC Director is required prior to concept proposal submission.
- c. Members of the PHAR Coordinating Center.
- d. Representatives of the Pulmonary Hypertension Association.

### ***Concept Proposals***

Formal P&P review and approval of all concept proposals will be required prior to authors or analysts being provided with analytic data. Concept proposals are summarized research plans and are required for any investigator seeking to analyze the PHAR data. Concept proposals are also used to request analytic support from the CC. All coauthors must have seen and approved the manuscript proposal prior to submission.

## **Concept Proposal Content**

Each concept proposal should be summarized in a separate Word document and uploaded on the online proposal template. ([link to proposal template here](#)). The concept proposal should include the following:

- a. Introduction: Rationale and background, brief.
- b. Research Hypothesis: Clearly state scientific questions to be addressed.
- c. Data: List variables to be used, sample inclusions/exclusions.
- d. Analysis plan and methods: Give detailed description of proposed statistical analyses. Please include the total sample size and any subsets of interest.
- e. References

Concept proposals should be no more than 2-4 pages in length, excluding the references. Proposals longer than 4 pages will not be reviewed. P&P policy requires authors to include the study name (i.e. The Pulmonary Hypertension Association Registry) at the end of their paper title. The only exceptions to this policy are when the Journal restricts the number of words allowed in the title or the paper combines data from multiple studies (then an abbreviation such as “The PHA Registry” or “PHAR” may be used, if possible).

Paper proposals will not be considered by the P&P committee unless it is feasible to begin data analysis within 12 months of proposal approval, based on the availability of sufficient endpoint data. This does not include unavailability of data due to technical problems, delays in data cleaning, or delays in data release.

Upon approval by the P&P Committee, the proposal will be assigned a manuscript number in the PHAR P&P database and will be visible online in the Table of Status and Authorship Information (on the P&P Web page, [link provided here](#)).

The P&P Committee, in consultation with the CC, will determine priorities for data analyses of manuscripts and abstracts to be performed by the CC. Analyses for other papers may start as soon as they are approved.

## **Submission**

Submission of all concept proposals will occur through the online P&P database located at: ([Once we have designed a submission form, will include a copy of this here with description of fields and required information](#))

## **Concept Proposal Guidelines and Policies**

### **Authorship**

There is no limit to how many primary authors (those listed by name) are to be listed on any paper. This will be determined by the final author list on the Proposal Submission Form. Authorship for non-primary authors will be written as “on behalf of the PHAR.”

Proposals with more than 3 authors at one site require justification from the first author. First authors are asked to explain how each coauthor will contribute to the paper. Examples include data collection, analysis, or help writing the paper.

While there is no limit to the number of named authors, authors should fulfill the [criteria for authorship](#) established by the International Committee of Medical Journal Editors. No more than two Steering Committee members should serve as authors on each proposal and the inclusion of junior investigators in lead roles is encouraged.

### **Formation of Writing Groups**

Usually the manuscript proposer will be designated as the Writing Group Chairperson and first author of the paper. In general, an investigator should not have more than two approved and active, unpublished manuscripts which haven't yet progressed to the pen draft stage in which he/she is the Writing Group Chairperson.

### **Writing Group Responsibilities**

The Writing Group Chairperson is responsible for all phases of manuscript preparation, from conception through publication. *These responsibilities include:*

- Preparation of concept proposal, paper outlines, the identification of data analyses needed, and submission of any interim status reports to the P&P Committee;
- Assignment of tasks to Writing Group members with clear deadlines for completion of these tasks and determination that the tasks are completed on schedule;
- Preparation and circulation of drafts for approval by each member of the Writing Group before submission of a Penultimate Draft to the P&P Committee and before submission to a journal;
- Determination of the order of authorship on the manuscript. A major criterion will be the effort and contribution made by each member of the Writing Group in the preparation of the manuscript;
- Choice of a journal to which the manuscript will be submitted;
- Correspondence with coauthors, communication with the CC and the P&P Committee, responses to reviews, and to journal editors.

The Writing Group Chairperson should contact each member of the Writing Group to discuss the outline of the paper, data analysis plan, and the responsibilities and assignments for each member. Members of the Writing Group are responsible for performance of tasks assigned by the Chairperson within the allotted time period. Each member is expected to actively participate in the preparation of the manuscript.

All coauthors should let the Writing Group Chairperson know of a change in contact information. Failure to respond within a reasonable amount of time to a Chairperson's request for coauthor feedback, could result in removal from the Writing Group.

If a Writing Group member does not accomplish the tasks assigned to him/her and has not contributed to the manuscript, the Writing Group Chairperson may request that P&P approve removal from the writing group. The chairperson must send an email to the P&P Program Coordinator requesting the removal of non-contributing members.

If the initial results lead to a split of the original paper into more than one manuscript, a new proposal should be submitted to the P&P Committee. The new proposal should be submitted via the online proposal submission form available on the Publications page of the website ([link provided when designed](#))

## ***Schedule for Manuscript Preparation***

The expected schedule for the development of a manuscript is described below. Deviation from this schedule must be approved by the P&P Committee. Failure to adhere to this schedule will prompt a review of circumstances. If it is determined that a manuscript is delinquent, this could be the basis for replacing member(s) of the Writing Group responsible for the delay, or for disbanding the Writing Group.

### **Draft**

For concept proposals that require CC statistical support, after notification by the P&P Committee of concept approval, an analyst will be assigned to the writing group. The Writing Group Chair with consultation from the Writing Group will have an initial discussion with the analyst to discuss the analysis plan and timeline for analysis completion. After the analysis is completed, the Writing Group will prepare a first draft. This process will be managed by the Writing Group Chair. A first draft will consist, at a minimum, of an Introduction, Methods and Results Sections. A draft compiled by the Writing Group Chair should be sent to the other members of the Writing Group for review. It is recommended that a response deadline of 4 (four) weeks be given to Writing Group members for comments back to the Writing Group Chair to prevent unnecessary delays.

### **Penultimate Draft**

The penultimate draft becomes due 4-6 weeks after the first draft comments are received from the Writing Group (see above). A penultimate draft should be sufficiently developed for subsequent submission to a journal. After review and approval of the penultimate draft by Writing Group members, the penultimate draft should be sent to the P&P Program Coordinator as an email attachment. Concept proposals are expected to reach penultimate manuscript draft stage within six months of P&P approval, or within six months of the availability of a CC analyst and related data readiness for the Writing Group.

Include the following required information with each new pen draft:

- a. PHAR manuscript number (provided upon concept approval)
- b. Confirmation that all coauthors have seen and approved the manuscript version sent for P&P review
- c. Specify one target journal for publication submission.

### **Journal**

Within thirty (30) days of receiving P&P Committee comments and verification confirmation, the revised manuscript will be circulated by the Writing Group chair to the Writing Group for final sign-off. The manuscript will immediately be submitted to a journal. A copy of the journal cover letter and final draft of the manuscript must be sent to the P&P Committee in addition to all coauthors.

The Writing Group Chairperson must keep the P&P Committee and the coauthors informed as to the manuscript's progress through journal review. Upon publication of the manuscript, the Writing Group Chairperson must provide either a reprint or copies of the final publication to the P&P Committee. If there are substantive changes made in the manuscript during journal review (major findings or conclusions, alterations of the sample, exclusion/inclusion of major covariates), the revised manuscript should be submitted to the P&P Committee for re-review.

## **Acknowledgements**

All publications using PHAR data shall use the following acknowledgement:

*The Pulmonary Hypertension Association Registry (PHAR) is supported by Pulmonary Hypertension Care Centers, Inc., a supporting organization of the Pulmonary Hypertension Association. The authors thank the other investigators, the staff, and particularly participants of the PHAR for their valuable contributions. A full list of participating PHAR sites and institutions can be found at [www.PHAssociation.org/PHAR](http://www.PHAssociation.org/PHAR).*

## **Data Analysis of PHAR Integrated Data**

Following approval of a concept proposal, investigators may request a dataset for local data analysis, or may request analysis support from the Coordinating Center. Investigators requesting datasets must first have a fully executed Data and Materials Distribution Agreement (DMDA) and complete a Data Request Form describing the complete list of variables requested for the analysis. The Data Coordinating Center will review all DMDAs prior to release of data to ensure that Data Use Agreements between PHCCs and the CC will be honored. Data will only be released for analysis to investigative groups with a qualified statistical analyst, as determined by the CC. Only de-identified data will be released for paper proposals using solely PHAR data. Sharing of data or results beyond the approved authors/analysts or analyses beyond those approved in the proposal or other violations of the DMDA may result in institutional and individual sanctions.

Guidelines for investigators to use in dealing with the Coordinating Center are:

- Plan systematically for the analysis of your data.
- Communicate with the assigned CC representative on the Writing Group for all requests and questions on analyses.
- Generate data requests in a timely fashion; requests will be allowed within the time window before and after the first draft.

## **Preparation and Submission of Abstracts for Submission to Conferences**

- New abstracts must be based exclusively on an approved concept proposals or submitted or published manuscripts.
- An abstract based on an approved paper should be submitted (online) to the P&P Committee for review no less than 2 weeks before the conference (abstract) submission deadline. It is strongly advised that authors submit abstracts well before this deadline, in order to allow sufficient time for revisions. There is no guarantee that abstracts submitted after the P&P deadline will be approved prior to the conference deadline.
- New abstracts must be submitted online using the PHAR web site (link provided). Please use the online PHAR Abstracts and Presentation Submission Form to submit a new abstract to the P&P Committee. This form is available on the Publications page of the PHAR Web site.
- The P&P Coordinator will notify the first author (via email) when P&P Committee approval is received.
- No abstract shall be submitted to any national or international organization for consideration prior to review and approval by the PHAR P&P Committee and sign-off from all coauthors. Any abstract submitted without these approvals may be asked to be withdrawn.

- If an abstract is not accepted upon its original submission, please let the P&P Coordinator know via email before you resubmit it to another conference.
- If the abstract is accepted, a copy of presentation materials (including tables and graphs) and text are to be submitted to the P&P Program Coordinator as an email attachment.

### ***Review of Proposal Materials***

All publication materials—concept proposals, penultimate drafts, and abstracts—will be reviewed by the P&P Committee on a monthly basis. The P&P Committee will meet on the **second Tuesday** of each month. The P&P Coordinator will review all proposal materials to verify that P&P policies have been followed, so as to avoid unnecessary delays upon review. The goal of P&P review is to ensure that research proposals are scientifically sound, use appropriate methodology, and are not duplicative of ongoing or past efforts.

### **Review/Deadlines**

The P&P Program Coordinator will make every effort to include all submissions in the next available P&P Committee teleconference. To allow sufficient time for processing and review, please submit all manuscripts by noon Pacific Time on Monday of the week before the next P&P teleconference. Refer to P&P Meetings and Paper Submission Deadlines located at the very top of the Publications page ([Website link here](#)) for teleconference dates and deadlines.

All materials submitted to the P&P Committee must first be reviewed and approved by all co-authors, with the status of coauthor approval indicated to the Committee at time of submission. If full Writing Group review and approval is not obtained, the Writing Chair must inform the P&P.

The P&P Committee will provide all review of concept proposals, penultimate drafts, and abstracts followed by a discussion during a P&P Committee conference call. Afterward, the author will be sent a summary of reviewers' comments.

If a proposal/pen draft/abstract is not approved by the P&P Committee, the draft will be returned to the Writing Group Chairperson with comments regarding the necessary revisions before resubmission. The Writing Group Chairperson will be responsible for the revision process, and should circulate the P&P Committee feedback to all authors, ensure that a plan is developed for responding to the requested revisions, and receive approval from all writing group members before a final draft is resubmitted to P&P.