



Standard Operating Procedure for a PHTS Research Study

The purpose of this document is to describe the steps of a research project and specifically list the tasks for the principal investigator. We always expect the process to be fully collaborative and we expect the process to result in a publication. The PHTS Scientific Committee is ultimately responsible for the entire process. The PHTS DCC at UAB will assist the PHTS Scientific Committee. The following steps of the entire research process are necessary to ensure both good science and good process.

1. Submission of a research proposal

The purpose of the proposal is to present the background, specific aims/hypotheses, and strategy for utilization of PHTS data, anticipated results and a brief timeline. In order to ensure a fair and timely process, applications will not be accepted from researchers who have research projects that have not yet resulted in a submitted manuscript. This requirement may be waived at the discretion of the Scientific Committee.

2. Review of applications by the Scientific Committee

The committee will review each proposal for both scientific merit and the ability of the PHTS data to answer the hypotheses. Before review of a proposal, the PHTS DCC will update the committee on the regulatory status of the applicant's institution: including current status of the local IRB approval, and current completeness of data. If necessary the committee will ask the applicant to participate in the conference call to present his or her proposal and/or answer questions about the proposal.

3. Notification of acceptance/rejection of proposal

The chair of the Scientific Committee will provide written notification of the proposal status to each applicant. In addition to acceptance or rejection, the committee may choose to delay a proposal for various reasons (e.g. additional data collection). The Scientific Committee will also create a writing group consisting of other PHTS Investigators.

4. Applicant becomes the principal investigator

Once a proposal is accepted, the applicant now becomes the principal investigator for the study also referred to as lead investigator. The lead investigator is responsible for all steps of the research project. The PHTS DCC will collaborate with the lead investigator but the primary responsibility for the research project belongs to the lead investigator. The lead investigator can provide suggestions for co-authors. As a general policy the nurse coordinator at the lead investigators hospital will be included as a co-author.

5. Detailed plan of work

The lead investigator will create a detailed plan of work including a quantitative review of the literature, specification of the endpoints, creation of templates for figures and tables, anticipated results of the analyses and a detailed timeline.

6. The research collaboration

The actual analyses will be a collaborative effort. The PHTS DCC will produce the requested analyses and will review these analyses with the lead investigator. The lead investigator is responsible for updating and including all members of the PHTS Writing Group assigned to his



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abstract, including scheduling of regular conference calls, email updates, etc. for all steps of the project including detailed analyses plans, abstract generation and manuscript preparation.

7. Abstract generation

The lead investigator will generate the abstract based on the collaborative analyses. The proposed abstract must be completed two weeks prior to the submission deadline. The lead investigator is responsible for distribution of the proposed abstract to the co-authors and to the current members of the PHTS DCC. Actual submission of the abstract will be done by the lead investigator. Once the principal investigator is notified that the abstract is accepted for presentation at a meeting, the principal investigator must notify the co-authors, and the UAB Research Team.

8. Presentation

The lead investigator is responsible for the presentation. As requested by the lead investigator the PHTS DCC will assist in preparation of the presentation. The PHTS DCC almost always prepares the figures and the tables. The lead investigator must circulate the presentation to the co-authors.

9. Manuscript

The lead investigator is responsible for generating the manuscript. Under the precise direction of the lead investigator, the PHTS DCC will produce the “journal ready” figures and tables. The lead investigator is responsible for circulating the manuscript to the co-authors and to the Scientific Committee. Ideally, the manuscript would be submitted to a journal at the same time of the ISHLT presentation (some scientific societies require this). The PHTS leadership strongly recommends that the manuscript be submitted at the time of presentation or very soon thereafter.