

WHAS Data Acquisition System Process Overview

The Woman's Health and Aging Study Data Acquisition System (version 1.0) is a web-based system that allows investigators to apply for access to WHAS data sets (www.jhpeppercenter.org/DAS). Designed to streamline the proposal submittal, review, and approval process, the system also promotes increased dialog between applicants and the members of the publication committees charged with reviewing the submitted proposals.

This document provides an overview of the process.

The process is divided into 5 phases: Proposal Completion and Submittal, Proposal Review and Scoring, Data Selection and Submittal, Data Selection Review and Approval, and Data Delivery. Each of these steps is described in greater detail below.

Approximate Timeline:

Step	Estimated Time to Complete	Whom Is Responsible
Proposal Completion and Submittal	Depends on the Investigator	The Investigator applying for access
Proposal Review and Scoring	14 days*	The Publication Committee of the Selected Study
Data Selection and Submittal	Depends on the Investigator	The Investigator applying for access
Data Selection Review and Approval	10 days	The Biostats Core (Qian-Li Xue and Karen Bandeen-Roche)
Data Delivery	10 Days	The Biostats Data Core (Don Baughman, Dennis Xu, Marcia Omondi, Tom Hoen)

* As of January 2005. Prior to this, the review period was 30 days

Proposal Completion and Submittal:

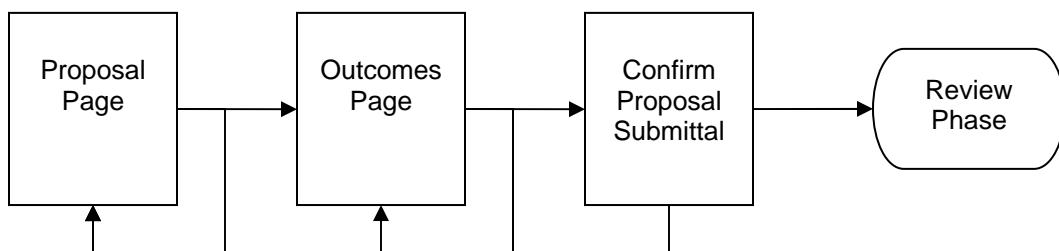
The first step to access WHAS data is to complete the proposal, submit and confirm it. To begin the process, select the **Enter New Proposal** link on the left hand menu bar. This will display the main proposal page. You will need to complete this, the following Outcomes page, and finally, the Confirm Submittal page. The buttons on the bottom of the page perform the following actions.

Button	Action
Save	Saves the information currently entered on the page and returns you to the same page. It is a good idea to regularly save your information, as the site will "time-out" after 20 minutes of inactivity and you could lose what you have entered. Keep in mind that even

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	though you may be typing information on the page, the site is not aware of this activity until you submit your page.
Save and Continue	Saves the information currently entered on the page and moves you to the next page.
Save and Exit	Saves the information on the page and returns you to the main page of the site
Exit without Saving	Does not save the information currently entered on the page (though information previously saved is untouched) and returns you to the main page of the site.

Below is a diagram of the Proposal Completion and Submittal process



The Proposal Page contains fields for entry of the purpose of the analysis, the study under which the proposal is being submitted, along with the aims and objectives, background/significance, hypotheses and analytical plan, among others.

The Outcomes page asks for one or more study outcomes. Each outcome includes a description, a definition, whether secondary variables need to be constructed, which primary variables make up the secondary variable, and the formulas for creating the secondary variables.

The Confirm page redisplays all of the information entered on the previous pages and can be reformatted for printing the proposal.

Once the investigator has completed the Confirm Proposal Submittal page and confirmed the proposal, notices are sent to proposal reviewers that a new proposal has been submitted, and the Review and Score Phase begins.

Review and Score Phase:

During the Review and Score Phase, publication committee members assigned to the proposal can review, make comments on, and score the proposal. When the committee members were notified that a new proposal awaits their review, they were also given a date by which they were responsible for completing the review. Typically, this is 14 days from the date the proposal was submitted.

Each comment left by committee members can be responded to by other committee members and by the investigator. Therefore, it makes sense for the investigator to regularly check the proposal for new comments.

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Scoring not only provides feedback on the relative merits of 4 separate aspects of the proposal (Significance of Work, Study Hypothesis, Study Aims, and Study Design), but also is the means by which the proposal is approved or disapproved. Scoring runs from 1 (Outstanding), to 5 (Unacceptable). A score of 1 or 2 indicates approval. A score of 3 or 4 indicates approval pending suggested changes (made in the comments section). A 5 indicates Disapproved. Typically, a reviewer will provide comments containing suggestions to improve the proposal before giving a score of 5.

On the Request Review page, the investigator sees an average of the scores from all of the reviewers.

At any time, the investigator can revise and resubmit their proposal. This would most likely be done after the reviewers have had the opportunity to comment on the proposal. If changes were suggested and the investigator has made those changes, they should indicate as such in the comments.

After all reviewers have scored the proposal, the proposal is marked that the review phase is completed. If the proposal was approved, the status is changed to indicate that the request is now in the third phase, Data Selection Review and Approval. If the proposal was not approved, the investigator is notified as such and the proposal is marked as completed.

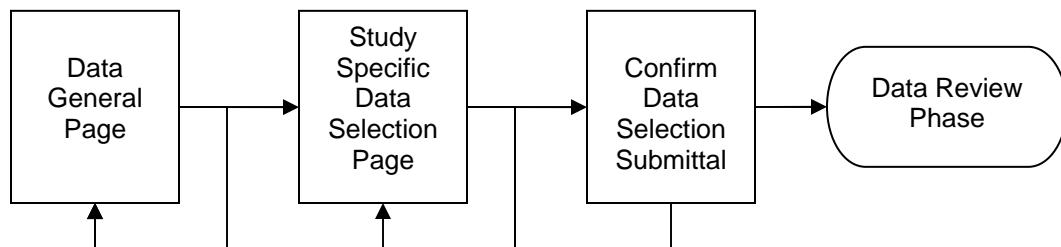
Data Selection Review and Approval Phase:

The Data Selection and Review stage allows the investigator to select the specific data elements that are pertinent to their proposal. There are two parts to the Data Selection information that the investigator is required to completed.

First, a Data General page is displayed where information on the data formats, among other information, is requested. Then, based on the Study selection chosen on the Data General page, the investigator will see lists of available data sets, organized by topics and rounds.

As with the Proposal submittal phase, the buttons at the bottom of the page allow the page to be saved periodically before moving on to the next page of the Data Selection phase.

Below is a diagram of the Data Selection Phase



Since there can be multiple Studies to chose from (WHASI, WHASII, Blood Analysis, etc), the investigator may see multiple Study Specific pages. All Data General

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information and Study Specific selections will be aggregated and reformatted on the Confirm Data Selection Submittal pages. Once the investigator confirms the Data Selection information, the WHAS Biostatistics group is notified that a new Data Request has been submitted and that it requires review.

Data Selection Review and Approval Phase:

Once notified of the new Data Selection Request, the Biostatistics member assigned to review the data request provides feedback on the request, may request changes in the selection of data, and approves the request.

As with the review phase of the proposal, comments may be left by the reviewer or the investigator, and the comments may be replied to.

If the reviewer requests that the selection be modified, the investigator can click the Modify Data Request button on the Review page. This will return the investigator to the Data General page, from which the investigator can modify the request. The request must be reconfirmed.

Once the Biostatistics reviewer has completed their review of the request, the Investigator will be sent a notification email of the status of their request. If approved, the request is sent to the WHAS Data Core. They are responsible for creating the data set specific to the investigator's request.

Data Delivery Phase:

The Data Delivery Phase begins when the Data Core is notified of the approved request. The expected delivery date of the data depends on the complexity of the request, whether new variables need to be created, and the priority assigned the proposal by the publications committee.

During this phase, the Data Core may contact the investigator to better clarify some of the aspects of the request and inform them on the progress of creating their data set. They will also work with the investigator on the most appropriate form of delivery.