

Investigator Guidelines:

Initially funded in 1993, the Women's Interagency HIV Study (WIHS) is the largest, long-term observational study of the natural history of HIV in women in the U.S. and follows both women who are HIV positive (80%) and a negative control group (20%). The WIHS is supported mainly by the National Institute of Allergies and Infectious Diseases (NIAID) as well as other co-funding NIH Institutes: the National Cancer Institute (NCI), the National Institute of Drug Abuse (NIDA), the National Institute of Child Health and Human Development (NICHD), and the National Institute of Dental and Craniofacial Research (NIDR). The WIHS comprises six metropolitan consortia nationwide: New York City Consortium (Bronx); State University of New York at Brooklyn; Washington, DC, Consortium; Los Angeles, Southern California Consortium; San Francisco/Bay Area Consortium; and the Chicago Consortium. Within each consortium there are two to six institutions or clinical sites involved, with a current total of 1,717 active participants being followed. All data goes through the WIHS Data Management and Analysis Center at Johns Hopkins University (WDMAC).

The WIHS calendar is based on two-six month visit cycles per year, October 1st – March 31st and April 1st – September 30th. All requests for initiating new sub-studies or for collaborative research projects within the WIHS must first be submitted in the form of a concept sheet. Once approved by the Executive Committee, new initiatives and protocol changes are generally instituted at the start of a visit cycle. Each site within each consortium must obtain their own institution's IRB approval prior to initiating new projects or significant changes in the protocol and all staff that will be involved will require appropriate orientation and/or training to carry out new protocols. In 2000, in addition to the core protocol, there was an initiative to revamp and re-prioritize one facet of the protocol, there were six national sub-studies and three collaborating RO1s, and multiple local, site-specific sub-studies being conducted within the WIHS.

Given the size of the WIHS structure and the volume of research being conducted, all investigators who are bringing new projects to the WIHS will need to consider three elements: time, communication, teamwork.

TIME – No one sub-study can take precedence. To get application paperwork from the consortia, or to organize a newly approved project, you will cue up behind others already in process – so start early. Notify WIHS Project Directors (PDs) well in advance of any due dates and be specific regarding your needs and time-table. Negotiation of the budget must be completed with each site before grant submission, and as soon as funding is approved or cuts are required, contact sites. You may contact each site directly, or start by contacting the Chair of the Project Directors' Group. This is a rotating position, so check with your WIHS contact to find out who is currently PD Chair.

COMMUNICATION – Organize your information into a comprehensive request. For example, if you are applying for a new grant, you may need the following: investigator biographies, other support information, certification of human subjects protection training, investigators' disclosure of financial interest, institutional agreement to participate, budgets, etc... A flurry of individual requests causes confusion and items are likely to be overlooked. Send requests to the PDs via electronic mail. Direct your data requests to the PD at WDMAC.

TEAMWORK – Each consortium within the WIHS has unique aspects to its organization and the requirements for carrying out additional projects may vary. The PD is intimately aware of the resources, organization, and limitations of her specific WIHS consortium. WIHS PDs are also experienced in organizing and coordinating multi-center studies. However, you must keep in mind that the WIHS consortia have limited administrative staff and while they can provide you with the information you request – you may have to be responsible for formatting some items to meet your needs. Once funded, you will be responsible for the bulk of the work required in organizing the protocol and developing data forms and consent templates. These should be reviewed by your local WIHS PD prior to submission to WDMAC. These forms are needed for IRB submission so must be distributed at least two months before you anticipate starting enrollment. As with the core study and all sub-studies of the WIHS, the PDs are happy to work with the investigator in a team effort to make your research a success and hope you will draw on their resources early in the process.