

<p style="text-align: center;">WOMEN'S INTERAGENCY HIV STUDY SECTION 2: ORGANIZATIONAL STRUCTURE</p>

A. CLINICAL SITES

- New York City Consortium – Principal Investigator, Dr. Kathryn Anastos; Project Director, Oluwakemi Sosanya. One site:
 - Montefiore Medical Center
- State University of New York at Brooklyn – Principal Investigators, Dr. Howard Minkoff and Dr. Deborah Gustafson; Project Director, Susan Holman. Two subsites:
 - SUNY Brooklyn – STAR Program
 - King’s County Medical Center
- Washington, DC, Consortium – Principal Investigator, Dr. Mary Young; Project Director, Lakshmi Goparaju. Three subsites:
 - Georgetown University Medical Center
 - Montgomery County Health Department
 - Inova Health System of Northern Virginia
- Los Angeles, Southern California Consortium (discontinued as of visit 37) – Principal Investigators, Dr. Alexandra Levine and Dr. Marek Nowicki; Project Director, Yvonne Barranday. Three subsites:
 - USC, Keck School of Medicine
 - Santa Barbara County Department of Health Services
 - Prototypes/W.A.R.N. + Women’s Health
- San Francisco/Bay Area Consortium – Principal Investigators, Dr. Ruth Greenblatt, Dr. Phyllis Tien, and Dr. Bradley Aouizerat; Project Director, Jennifer Cohen. Four subsites:
 - Highland Hospital
 - EBAC
 - San Francisco General Hospital
 - Mount Zion Hospital
- Chicago Consortium – Principal Investigator, Dr. Mardge Cohen; Project Director, Kathleen Weber. Four subsites:
 - Cook County Hospital, CORE Center
 - University of Illinois at Chicago
 - Rush-Presbyterian-St. Luke’s Medical Center
 - Northwestern Memorial Hospital
- Atlanta, Georgia – Principal Investigators, Dr. Igho Ofotokun and Dr. Gina Wingood; Project Director, Sara Sanford. One site:
 - Emory University

- Chapel Hill, North Carolina – Principal Investigator, Dr. Ada Adimora; Project Director, Catalina Ramirez. One site:
 - University of North Carolina at Chapel Hill
- Miami, Florida – Principal Investigators, Dr. Margaret Fischl and Dr. Lisa Metsch; Project Directors, Hancy Brignol and Lillian Colon. One site:
 - University of Miami
- Birmingham, Alabama – Principal Investigators, Dr. Michael Saag, Dr. Mirjam-Colette Kempf, and Dr. Deborah Konkle-Parker; Project Directors, Karen Savage and Venetra McKinney. Two sites:
 - University of Alabama at Birmingham
 - University of Mississippi at Jackson

B. NATIONAL COMMUNITY ADVISORY BOARD

A Chair and Co-chair of the NCAB are elected annually to serve as representatives to the Executive Committee. NCAB Representatives are also assigned to participate on WG conference calls. NCAB Members are invited to all semiannual WIHS EC Meetings and may attend one “conference of choice” annually, as site budgets permit.

C. WIHS DATA MANAGEMENT AND ANALYSIS CENTER (WDMAC)

Johns Hopkins University, Bloomberg School of Public Health

- Principal Investigators, Stephen Gange, PhD, and Elizabeth Golub, PhD
- Project Director, Christine Alden, BA
- Assistant Project Coordinator, Eryka Wentz, MA
- Research Program Coordinator, Owen Amadin, BS

Project Tracking. WDMAC is in charge of tracking WIHS projects and updating study management (EC) twice per year on the status of these projects. This process ensures that investigators are held accountable to follow through with completion of their WIHS proposals. WDMAC also has the following responsibilities: sending letters of approval or disapproval for submitted concept sheets and manuscripts, and assignment of co-authors for WIHS publications (please see the **Publication Policy, MOO Section 3**, for detailed information regarding the assignment of co-authors).

EC Conference Calls. WDMAC is responsible for soliciting agenda items, and distributing agendas for all EC conference calls. WDMAC is responsible for taking and posting minutes. WDMAC will work with the Chair of the EC in performing these duties.

D. NIH INSTITUTES

- NIAID – Program Officer, Joana Roe; Science Officer, Gerald Sharp
- NICHD – Program Officer, Denise Russo
- NIDA – Program Officer, Richard Jenkins (backup, Katherine Davenny)
- NCI – Program Officer, Geraldina Dominguez
- NIMH – Program Officer, Deborah Colosi

E. EXECUTIVE COMMITTEE

All decisions regarding WIHS are made by the Executive Committee (EC). The EC membership includes NIH Program Officers, site and WDMAC Principal Investigators, site and WDMAC Project Directors, and NCAB representatives. Voting members include the eleven PIs, the five NIH Program Officers, and the NCAB chair (for a total of 17 votes).

F. SCIENTIFIC ADVISORY BOARD

This group was replaced by the Scientific Chairs Committee at the beginning of WIHS IV.

G. SCIENTIFIC CHAIRS COMMITTEE (SCC)

The Scientific Chairs Committee was discontinued at the end of WIHS IV.

H. WIHS WORKING GROUPS

Working groups are in charge of providing expert input to the WIHS EC on specific areas of form and protocol development, as well as scientific initiatives.

1. ADMINISTRATIVE WORKING GROUPS

- National Community Advisory Board (NCAB) – chair, Marta Santiago
- Project Directors – chair, Susan Holman
- Data Management – chair, Sally Urwin
- Laboratory/Specimen – chair, Yvonne DeSouza
- WIHS Specimen Allocation Committee (WSAC) – chair, Marek Nowicki

2. SCIENTIFIC WORKING GROUPS

- Behavior/Substance Use – co-chairs, Mardge Cohen and Janet Turan
- Cancer –chair, Lisa Flowers; co-chair, Eric Seaberg
- Epidemiology – chair, Ada Adimora
- Genetics – chair, Brad Aouizerat
- Hepatitis /Liver Disease – co-chairs, Marior Peters and Audrey French
- HPV – chair, Howard Strickler
- Pathogenesis – co-chairs, Betsy Herold and Mike Saag
- Metabolic/Vascular – chair, Neale Weitzmann
- Neurocognition – chair, Pauline Maki; co-chair, David Vance
- Pharmacology – chair, Monica Gandhi
- Gynecology – chair, Stewart Massad
- Pregnancy – chair, Elizabeth Golub
- Female Genital Tract – chair, Betsy Herold

I. WIHS COMMUNICATIONS PROCEDURES

1. RESOLVING INQUIRIES WITHIN WIHS SITES

The WIHS Manual of Operations was designed to address most questions pertaining to study operations and protocols. There are times, however, when unusual or unpredictable situations arise that may require further explanation than what is addressed in the operations manual. In these cases, staff members at the WIHS sites

are encouraged to bring their questions and concerns to their local Project Director (or her designee).

When a question requires further clarification, the site's Project Director should redirect the question to WDMAC. All inquiries should be addressed to the WDMAC Project Director (Christine Alden) or Assistant Project Coordinator (Eryka Wentz). They can be contacted by phone or e-mail (calden@jhsph.edu or ewentz@jhsph.edu).

2. COMMUNICATION BETWEEN WDMAC AND WIHS SITES

All project-related correspondence and communications between field sites and the coordinating center are documented and filed at WDMAC. WDMAC uses two types of correspondence to document and communicate information to field staff: (a) numbered communication memos; and, (b) site-specific memos. (See distribution details below.)

If an inquiry pertains to an important matter involving all WIHS field staff, then a *numbered communication memo* will be written and distributed study-wide. Any site-specific inquiries (not necessarily pertaining to all WIHS sites), which involve important protocol clarification issues, will be addressed via a *site-specific memo*.

a. **Numbered Communication Memos.** These important memos are numbered to ensure that each one has been received and filed appropriately by the WIHS sites. If a memo is lost or misplaced, site staff should download that memo from the WIHS Administrative web site. Each numbered communication memo should be filed on-site in a Communication Memo Book. Each WIHS site (including all subsites) should have a current Communication Memo Book that is easily accessible to site staff for reference. WDMAC distributes the numbered communication memos via email to the following WIHS personnel:

- NIH Program Officers, Principal Investigators, Project Directors, NCAB Representatives, Working Group Chairs, Site Data Managers, and other Site-Specific Personnel.

NOTE: It is the responsibility of the Project Directors to ensure that all WIHS staff members in their respective consortium are given copies of the numbered communication memos (i.e., site coordinators, administrative staff, lab personnel, abstractionists and protocol-specific staff, etc.). Please contact WDMAC to add site personnel to the email distribution list.

b. **Site-Specific Memos.** Questions or problems from a site staff member should be sent via email to the WDMAC Project Director (Christine Alden, calden@jhsph.edu) or the WDMAC Assistant Project Coordinator (Eryka Wentz, ewentz@jhsph.edu). WDMAC will then respond to the staff member who made the original inquiry, via email. The staff member who made the inquiry should share WDMAC's response with other site staff, if appropriate.

J. DISTRIBUTION OF STUDY-WIDE CORRESPONDENCE AND MATERIALS

In addition to communication memos, which pertain specifically to field operations, WDMAC may deliver other necessary documents via first class U.S. Mail, Priority Mail, FedEx and email. The method used will depend on the time-sensitivity of the material and/or the recipient's preferred method of receipt. In order to facilitate timely and efficient

distribution, sites should inform WDMAC of all staffing changes (i.e., name, title, address, phone, fax, email address, etc.) via the online directory (on the Administrative web site).

The WIHS Administrative web site and Forum are two separate entities. You can access the Forum from the WIHS web site, but, because the Forum is a separate entity, you will need to log in a second time with your Forum-specific password. All posting of WIHS concept sheets, manuscripts and abstracts takes place on the WIHS Forum.

The Administrative web site provides study information (outlined below). The Forum is where concept sheets, manuscripts and abstracts and their reviews are posted. In addition, the Forum contains the working group bulletin boards, where working group correspondence and minutes from the groups' meetings are posted; both the WIHS and the MACS working group conference call monthly schedules; visit changes; potential funding opportunities; conference opportunities; requests for funding; and helpful WIHS information, such as lists of transfer IDs, dropped IDs, etc; and Apollo bugs.

Please see WIHS Communication Memo #435, e-mailed on April 1, 2005, for more information on using the Forum.

There is also a Public WIHS web site. This site is used for the dissemination of information to the general public, without use of a password.

The address for the unrestricted **Public** web site is <http://statepiaps.jhsph.edu/wihs/>. This page is accessible to the general public.

The address for the restricted **Administrative** web site is <http://statepiaps.jhsph.edu/wihs/admin/>. This page is accessible only to WIHS personnel with a valid password assigned by WDMAC.

The address for the **Forum** is http://statepiaps2.jhsph.edu/WIHS_forum/index.php. This page is accessible only to WIHS staff with a valid password assigned by WDMAC.

Please contact WDMAC for assignment of IDs and passwords for WIHS Admin web site and Forum access for new investigators.

1. WIHS ADMINISTRATIVE WEB SITE

The WIHS Administrative web site contains links to various WIHS study materials.

- 1) LINKS LOCATED ON LEFT, DARK PURPLE BAR (ACCESSIBLE FROM ALL PAGES WITHIN THE SITE):
 - **Home** – This link takes the user back to the home page of the WIHS Administrative web site.
 - **Forum** – This link takes the user to the WIHS Forum. A separate login for the Forum is required.
 - **WIHS News** – This link contains information that is of interest to investigators, such as information on new working groups, WIHS semiannual meetings, and other relevant WIHS-related information.
 - **Directory** – This is the electronic version of the WIHS staff directory. Additions or changes to the directory should be submitted to WDMAC by using the form located in this page.

- **Publications** – This page contains four links:
 - The *WIHS Dossier*, a PDF, in presentation form, of selected WIHS publication data. This presentation is updated every six months, prior to the semi-annual WIHS EC meetings.
 - The *WIHS Archives*, a PDF list of all WIHS publications. This list is updated in real time.
 - The *WDMAC Report*, a PDF, in presentation form, of selected WIHS data. This report is generated every six months, prior to the semi-annual WIHS EC meetings. As the Report contains unpublished data, it should not be shared with non-WIHS investigators.
 - The *WIHS/MACS Searchable Database*, where users can search for a MACS or WIHS publication by keyword.
 - **Presentations** – Contains all available presentations presented at the WIHS EC and joint WIHS/MACS semiannual in-person meetings.
 - **WIHS Public Web Site** – This link takes the user to the WIHS Public web site.
- 2) LINKS LOCATED UNDER EC/WORKING GROUP RESOURCES:
- **EC Conference Call Dates** – List of scheduled EC conference call dates for the current year.
 - **EC Minutes** – This link contains EC conference call minutes for the current year.
 - **EC Minute Archives** – This link contains Scientific and Administrative EC conference call minutes categorized by year, from 1997 to the year prior to the current year. Please note that minutes for all other conference calls (e.g., WG) are posted to the Forum. Minutes for other conference calls taken prior to 2005 can be found in the “old bulletin boards” link, in the EC/Investigator Resources section.
 - **SCC Minute Archives** – This link contains SCC conference call minutes categorized by year, from 2008 to 2012.
 - **Working Group Members** – Contains a list of all currently active WIHS working groups, including the groups’ members and chairs.
 - **Old Bulletin Boards** – This link contains all old WIHS bulletin boards – all scientific, community, EC and visit changes boards – prior to implementation of the WIHS Forum.
- 3) LINKS LOCATED UNDER INVESTIGATOR RESOURCES:
- **Concept Sheet Information** – This link contains PDFs of approved WIHS concept sheets. They are categorized by year and by topic. There are links to Excel spreadsheets containing CS co-authors, all approved CS, and

genetics projects, as well as status updates for WDMAC analytic projects, NIDA-funded projects, and NIAID unobligated funding projects.

- **Investigator Information** – This link contains information for internal and external investigators.
 - ❖ Long and short WIHS acknowledgments
 - ❖ Oral substudy acknowledgements
 - ❖ Definition of HAART – current definition used in WIHS summary files
 - ❖ Investigator guidelines for initiating WIHS substudies and research collaboration
 - ❖ Requesting WIHS specimens – specimen request forms for DNA and WIHS central repository, as well as instructions for submittal
 - ❖ Publication policy
 - ❖ Contact persons for the WIHS
 - ❖ Links to the following: RePORTER; HIV Protease Database; NIH RFA Home Page; WIHS/MACS searchable publication database; NA-ACCORD homepage; WIHS genetic consent information
- **WIHS PIs and PDs** – List of all WIHS Principal Investigators and Project Directors by site.
- **Requesting WIHS Specimens** – Instructions for requesting specimens from the WIHS central repository and DNA repository, as well as links to specimen request forms.
- **Forms** – This link contains all of the forms investigators will need to fill out for concept sheets, manuscripts, abstracts, conference call requests, and notification of the publication of his or her manuscripts.
 - ❖ The current version of the *Concept Sheet Submission Form*. This form should be used for the submission of all proposed concepts to WDMAC. Concept sheets submitted on the wrong form will be returned to the author to be resubmitted on the correct form.
 - ❖ The current version of the *Manuscript Submission Form*. This form should be used for the submission of all manuscripts to WDMAC. Manuscripts submitted on the wrong form will be returned to the author to be resubmitted on the correct form.
 - ❖ The current version of the *WIHS Publication Submission Form*. This form should be used for the submission of all publication notifications to WDMAC. Use this form when a manuscript is submitted to a journal, and then again when the manuscript is either published or rejected by the journal. This form will help WDMAC keep track of all WIHS publications and will ensure they are properly archived.
 - ❖ The current version of the *PIR Concept Sheet Review Form*. This form should be used by Principal Investigator Reviewers (PIRs) when

reviewing a concept sheet. This form should be posted as a reply to the original concept sheet thread on the WIHS Forum.

- ❖ The current version of the *PIR Manuscript Review Form*. This form should be used by Principal Investigator Reviewers (PIRs) when reviewing a manuscript. This form should be posted as a reply to the original manuscript thread on the WIHS Forum.
 - ❖ The *Conference Call Request Form*. This form contains information on requesting a new conference call and should be submitted to Christine Alden (calden@jhsph.edu) to request arrangement of a survey or conference call.
 - ❖ The *DNA Repository Checklist Form* must be filled out upon approval of a concept sheet requesting DNA from the WIHS DNA Repository, and sent to the WDMAC Project Director. This form will then be forwarded to the Genetics working group chair.
 - ❖ The *Repository Request Checklist Form* must be filled out prior to submitting a specimen request. This form should be sent to the WDMAC Project Director.
- **Dossier** – The WIHS Dossier, a PDF, in presentation form, of selected WIHS publication data. This presentation is updated every six months, prior to the semi-annual WIHS EC meetings.
 - **Publications** – This page contains four links:
 - The *WIHS Dossier*, a PDF, in presentation form, of selected WIHS publication data. This presentation is updated every six months, prior to the semi-annual WIHS/EC meetings.
 - The *WIHS Archives*, a PDF List of all WIHS publications. This list is updated in real time.
 - The *WDMAC Report*, a PDF, in presentation form, of selected WIHS data. This report is generated every six months, prior to the semi-annual WIHS EC meetings. As the Report contains unpublished data, it should not be shared with non-WIHS investigators.
 - The *WIHS/MACS Searchable Database*, where users can search for a MACS or WIHS publication by keyword.
 - **Presentations** – Contains all available presentations presented at the WIHS EC and joint WIHS/MACS semiannual in-person meetings
- 4) LINKS LOCATED UNDER STUDY ADMIN / TRAINING:
- **Certifications** – Certification history for body habitus training, interviewer evaluations, WIHS III neurocognitive training, and WIHS laboratories.
 - **Clinical Training** – Links to training documentation for: DXA procedures, blood pressure measurements, the gynecological and breast exam,

lipodystrophy training, neurocognitive training, the oral exam, the visual inspection guide (for F07), and hair collection (QA and training video).

- **Communication Memos** – This link contains all WIHS communication memos categorized by year from 1994 to present. There is also a link on this page to a list that describes the contents of each communication memo.
- **Data Management Training** – Links to training documentation in the following categories:
 - **Use of WIHS Data** – Data Distribution Schedule; Overview of WIHS Data Collection Forms; Overview of WIHS Summary Files; How to use the Data CD; and Guidelines for Processing Viral Load Data.
 - **Visit Scheduling** – Visit numbers and time intervals; and Description of calendar based visit schedule.
 - **Miscellaneous** – List of WIHS subsites; Role of the Data Coordinating Center; How to Request Specimens; and WIHSIDs of Dropped Participants.
 - **Apollo** – Overview of Apollo; and How to Use the Apollo Query Function.
- **Data Availability** – Provides information on the data available in the WIHS. Provides specific information on WIHS data collection overview; core data collection; medication use; substudies; definitions; Biospecimen Research Database; blood collection and processing; blood collection tubes and assay compatibility; assays; and other.
- **Interviewer Training** – Links to interviewer training documentation:
 - **Interview-related Research principles** – presentation and notes.
 - **Training and Evaluating Interviewers in the WIHS** – presentation and notes.
 - **WIHS IV Neurocognitive Protocol Interviewer Training** – videos for all NC battery components – administration and scoring.
- **Pronunciations** – Audio and visual pronunciation guides for medications and other terminology used in the WIHS interview (under construction).
- **Visit Forms & MOO** – This link contains complete sets of WIHS forms and manuals of operations by visit. It also contains a link to Excel spreadsheets with the most recent form and QxQ versions and the most recent response card versions.
- **Visit Training** – This link contains visit changes and training documentation categorized by visit number.
- **WAT Tutorials** – The WAT (WDMAC Analysis Tutorials) are designed to enhance the programming community within WIHS; providing a common foundation of knowledge, language and understanding to

programmers at each WIHS center. WAT highlights valuable programming tools developed for the SAS platform.

5) LINKS LOCATED UNDER DATA MANAGEMENT:

- **Apollo Information** – Links to Apollo user tasks by month, and Apollo user information presentations.
- **Codebooks** – Links to all WIHS codebook files, visit 7 through present. Also included are descriptions and codebooks for all WIHS summary files.
- **Variable Index Files** – Links to Excel spreadsheets containing all variables from both the raw form files and the WIHS summary files. Also included on this page are spreadsheets listing historical use of variables and archived laboratory results.
- **WIHS Visit Intervals & Data Distribution**

b. WIHS Forum

1) The WIHS Forum is composed of the following main forums (for more information on using the Forum, please refer to communication memo # 435):

- **Concept Sheets** – This board contains concept sheets posted for EC review and approval. The WDMAC Research Assistant is in charge of posting all concept sheets. Personnel should click on the appropriate concept sheet thread to view and post comments. Contains a sub-forum for WHIN-related proposals and P01 projects.
- **Manuscripts** – This board contains manuscripts posted for EC review and approval. The WDMAC Research Assistant is in charge of posting all manuscripts. Personnel should click on the appropriate manuscript thread to view and post comments.
- **Requests for Funding** – Contains NIAID unobligated funding proposals, NIDA funding proposals, and NCI supplemental co-funding proposals by year/cycle. This board also contains progress reports for projects supported by unobligated and NIDA funding.
- **WIHS V Renewal** – Contains links to the Funding Opportunity Announcement (FOA) and questions and answers about the FOA published by NIAID.
- **WIHS IV Drafts and Documentation** – Contains draft sections of the WIHS IV renewal application; the final scientific agenda; and the study section comments. Contains sub-forums for biosketches for WIHS IV core investigators and WIHS IV Scientific Agenda progress reports.
- **WIHS Working Groups** – This board contains all of the working group bulletin boards. Minutes, action items and other information that pertains to each group should be posted under the respective bulletin board. Notes from STATEPI programmers meetings are included on this forum as a password-protected thread, “STATEPI.”

- **Visit Changes** – This board contains changes, comments and revisions to forms and protocols for upcoming visits. All proposed changes should be posted by the deadline specified in the visit timeline communication memo. Prior to the start of a new visit, the EC will review all comments posted and decide which will be implemented for the new visit. Old visit changes boards (prior to visit 23) can be accessed on the WIHS Administrative home page in the “old bulletin boards” link (begins with visit 17).
- **MACS Conference Calls** – This board contains a list of MACS working group conference call times and call-in information. This information is posted every month.
- **WIHS Conference Calls** – This board contains a list conference call times and call-in information. This information is posted every month.
- **Abstracts** – This board contains information on upcoming HIV and AIDS conferences. It also contains abstracts from WIHS investigators. See the WIHS Publication Policy (MOO, Section 3) for the WIHS abstract submission and review policy.
- **Funding Opportunities** – This board includes announcements about upcoming external funding opportunities for all WIHS investigators.
- **Conference Opportunties** – This board includes conference announcements and calls for abstracts.
- **Helpful WIHS Instructions** – This board includes helpful information, such as lists of transfer ids, visit windows, dropped ids, etc., as well as information on how to subscribe to bulletin boards on the WIHS Forum. WIHS personnel with access to the Forum may post helpful information to this board as they see fit.
- **Apollo Bugs** – Apollo users can report bugs found during use of the Apollo data entry system.

2) **ADDITIONAL FORUM FEATURES:**

- **User CP** – The user can edit his or her signature, email address, password, profile, as well as set up event reminders and much more. The user may also subscribe to a particular forum to be notified when new posts are made to that forum.
- **FAQ** – This link contains generic questions and answers about features on the Forum.
- **Members List** – This link contains the usernames of all WIHS personnel who have access to the forum.
- **Calendar** – This link contains times, dates and call in information for all MACS and WIHS conference calls. It is updated every month.

PLEASE REMEMBER TO LOG OFF OF THE FORUM WHEN FINISHED.

For technical questions or problems regarding access to the WIHS Administrative web site or Forum, contact Eryka Wentz (ewentz@jhsph.edu) or Won Yoo (wyoos@jhsph.edu). For assignment of a username and password to the WIHS Administrative web site or Forum, please contact Eryka Wentz. **Individuals are encouraged to post their own documents directly to the Forum.**

Individual sites are encouraged to develop their own local web sites. WDMAC will provide a link to these sites from the WIHS Public web site. Maintenance and control of these local resources are the responsibility of sites, not WDMAC.

c. WIHS Public Web Site

The WIHS Public web site (<http://statepiaps.jhsph.edu/wihs/>) provides the general public with information about the WIHS and its sponsors, the WIHS National Community Advisory Board (NCAB), contact information for WIHS personnel, and an archive and searchable database of WIHS publications. It is also a place where outside investigators can find information on collaborating with and submitting proposals to the WIHS. WIHS participants may also use the site to find links to the WIHS clinic of which they are a member.

K. PROCEDURES FOR IMPLEMENTATION OF PROPOSED NEW PROTOCOLS AND FORMS

a) Timeline

All proposals for new protocols should be submitted to the EC for review as a concept sheet (see the Publication Policy, Section 3 in the MOO, for further information). The EC will evaluate relevance to WIHS core aims and hypotheses and determine if there is duplication with other WIHS initiatives. A clear, practical and focused proposal is necessary for the EC to adequately evaluate the success of a protocol. The concept sheet should serve as a starting point for the final protocol.

- i. Any site(s) or investigator(s) interested in starting a new protocol or form should discuss this with their site PI and the appropriate working groups. These consultations should take place at least six months prior to the start of the new visit at which implementation is anticipated. The working groups will evaluate the protocol and forms for feasibility at least three months prior to the start of the visit.
- ii. Drafts of new protocols and forms are due to WDMAC prior to the time of the EC's approval call. This call takes place approximately three months prior to the start of a new visit (i.e., in January for visits starting April 1, and in July for visits starting October 1) and is announced in the visit timeline communication memo.
- iii. Form revision and integration of a new protocol into the core WIHS protocol will take place over the next month following EC approval.
- iv. New protocols and forms are sent to the sites for a piloting period two months before the start of a new visit, if appropriate.
- v. New protocols and forms are finalized one month prior to the start of a new visit.

b) All protocols must include information on the following:

- i. Purpose
- ii. Hypotheses and scientific aims
- iii. Background and significance
- iv. Study procedures or research design and methods
- v. Local IRB approval
- vi. Eligibility of sites and participants
- vii. Equipment and supplies, if necessary
- viii. Scheduling of a separate visit or incorporation into the core visit
- ix. Specimen collection, methods, and shipping
- x. Data reporting

c) Proposals for additional specimen collection

If the protocol requires additional specimen collection beyond those specimens typically collected at the core visit, the Project Director and Lab/Specimen working groups should review the protocol. Concept Sheet and protocol authors should consider and address the following questions prior to submission to the EC for review:

- Are fasting specimens preferred? How long should participants fast prior to the draw? Cite reasons for fasting if necessary, e.g., ways in which non-compliance would confound results.
- Suggestions for integration into existing WIHS core blood draw order.
- Describe preferred collection methods, for example:
 - i. Venous blood should be collected into an SST by standard phlebotomy techniques.
 - ii. Let blood clot 30 minutes in a vertical position.
 - iii. Within one hour of blood collection, centrifuge SST for ten minutes in a swinging bucket centrifuge or 15 minutes in a fixed angle centrifuge at 1,100 to 1,300 X gravity.
 - iv. Aliquot 1 mL of serum into an appropriately labeled cryovial.
 - v. Freeze cryovial within eight hours of collection. Refrigerate separated serum prior to freezing.

d) Proposals for additional laboratory testing

If the concept sheet/protocol requires clinical laboratory testing, the Project Director and Lab/Specimen working groups should also review the protocol. The scientific writers of the protocol should research and provide the following information prior to review by the EC:

- How will test results be reported to WDMAC?

- Test name(s) and expected results
- Testing facility (2 Contacts, Phone, Fax, Email, Shipping Address)
- Testing facility's test code
- Preferred and alternate draw tube type(s)
- Preferred and alternate sample type(s)
- Minimum volume to run assay/test once
- Recommended specimen volume
- Laboratory Fee: \$/sample

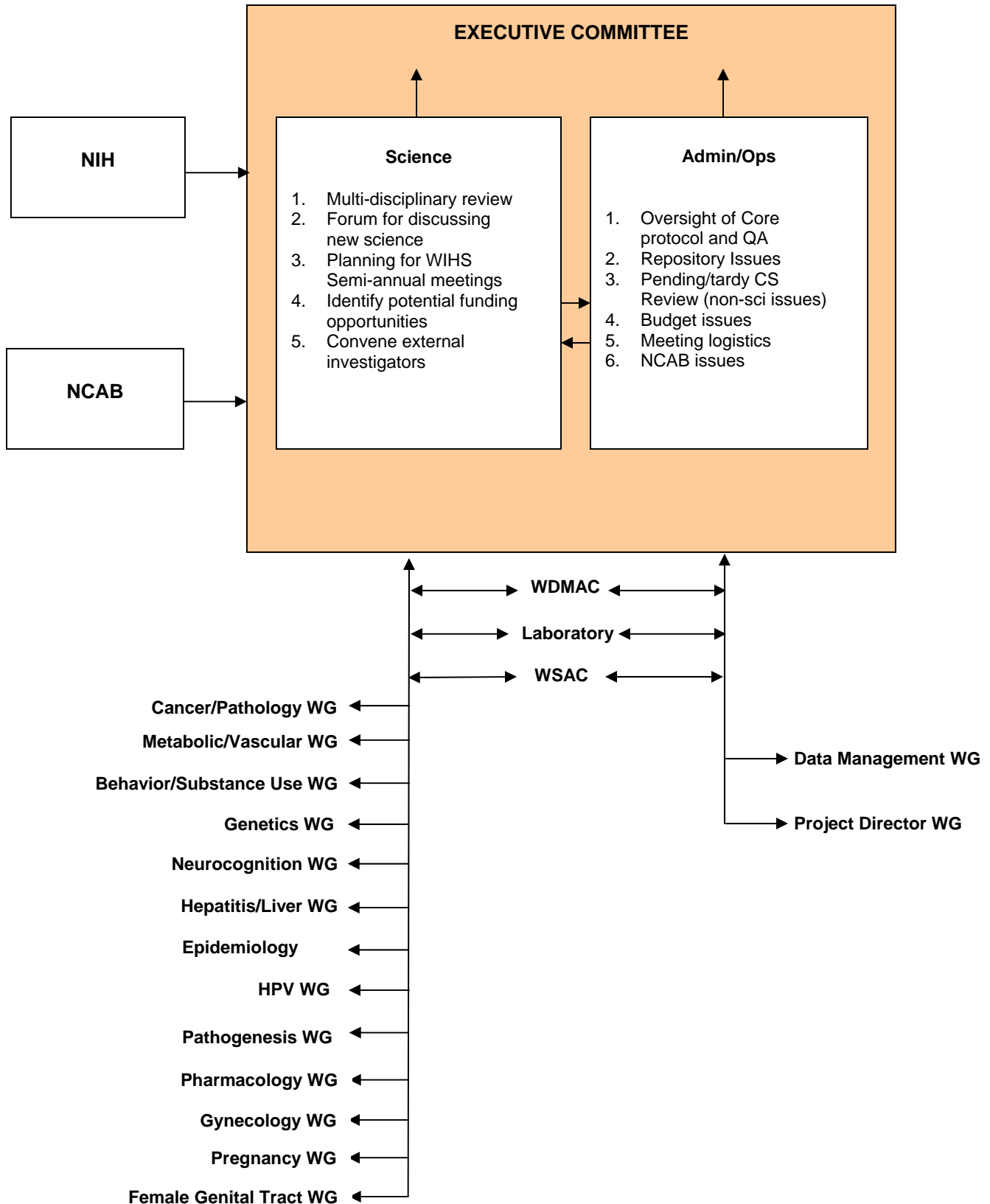
Sample acquisition by testing facility:

- Who will provide supplies to collect and process specimens?
- What are courier / shipping costs?
- Will specimens be centrally or locally tested? If centrally, what shipping schedule suits the needs of sites and testing facility? How will sites be billed for testing?
- What are shipping and manifest requirements?

e) Working Group Review

Appropriate working groups should be given ample time to review the draft protocol, e.g., if a concept sheet or protocol pertains to cancer research, a draft should be reviewed by the Cancer working group prior to submittal for EC review. The PD and Lab/Specimen working groups should also be consulted early in the development process for assessment of feasibility and practical issues regarding implementation of a protocol.

APPENDIX A: OVERVIEW OF WIHS ORGANIZATIONAL STRUCTURE



APPENDIX B: WIHS PUBLICATION PROCESS

Investigator has an idea for a new study or analysis (based on the WIHS publication protocol). . .

1. **Write a concept sheet** by filling out the *concept sheet submission form* and submit to WDMAC (wdmac@jhsph.edu) for posting and EC review. Please complete the form in full.
 - a. If the submitted concept sheet is regular priority, it is assigned a Principal Investigator Reviewer (PIR) as well as the following, if needed: a Project Director Reviewer (PDR), if new protocol or site burden is being proposed; a Lab Reviewer (LR), if collection of new specimens, or withdrawal of specimens from the central repository is proposed; and/or a Genetics Reviewer (GR). Regular priority concept sheets are given a 12-day review period for all EC members and a deadline of two weeks for the PIR.
 - i. Site-specific concept sheets involving only one site do not need review by a PIR, but do require approval by the site's Principal Investigator. The site's Principal Investigator should post approval to the respective thread on the forum. The concept sheet will be circulated as usual. Site-specific concepts sheets will be assigned a PIR, PDR, LR and/or GR if central WIHS resources (e.g., funding, repository specimens, WDMAC analysis time, etc.) are being requested.
2. **A README number is assigned after approval, and the research/testing phase begins.** WDMAC is responsible for assigning the README number. This number will be used in all ensuing communication regarding the project through publication. Upon approval, WDMAC determines whether or not a concept sheet requires co-authors from all the sites and if so, is in charge of soliciting for and posting co-authors.
 - a. Ideal time frame of project progress after EC approval (please note that these time frames will vary if a project requires specimen withdrawal, new protocol implementation, etc., but investigators should proceed with manuscript writing as soon as possible and without delay):
 - i. Obtain data set = 0.5 to one month after approval
 - ii. Writing group/co-authors established = two weeks to one month after approval
 - iii. Preliminary statistics = two months after approval
 - iv. Draft of manuscript = three months after approval
 - v. 2nd draft of manuscript with co-author comments = three to four months after approval
3. **Manuscript submission** – the ensuing manuscript is due four months to one year after the concept sheet approval date. Please email the full, co-author-approved manuscript, along with a lay language summary and *manuscript submission form* to WDMAC, (wdmac@jhsph.edu), for posting.
 - a. All manuscripts are assigned a PIR, whether from site-specific or core concept sheets. The review period for manuscripts is two weeks.
4. **Journal submission** – after a manuscript is approved by the EC, and all co-authors have approved the final version, the investigator may submit the manuscript to a journal of his or her choosing. The investigator must keep WDMAC up-to-date regarding the status of submission and rejection/approval notifications, as WDMAC tracks and notifies the EC upon acceptance and/or publication of a scientific article. The lead investigator of the manuscript should provide WDMAC with the full final citation, along with a PDF version of the published paper. Data sets should also be sent to WDMAC upon publication for archival purposes.