WOMEN'S INTERAGENCY HIV STUDY

SECTION 3: PUBLICATION/PUBLICITY POLICY

I. PUBLICATION POLICY

A standardized publication policy is essential for the WIHS to ensure the main goal of the study is met – to provide the public with information on women with HIV and AIDS, mainly through publication in scientific journals. Application of the policy will allow the WIHS to track scientific concepts as they undergo various stages in preparation for publication; therefore, all investigators who wish to use and publish data from the WIHS **MUST** follow the publication policy below.

A. CONCEPT SHEETS (CS)

Submission of concept sheet proposals is required for all proposed investigations involving analyses using existing data sets, the collection of new data (questionnaires, clinical and physical measures), and/or use or collection of laboratory specimens. Proposals must be submitted to the WIHS Data Management and Analysis Center (WDMAC) electronically (wdmac@jhsph.edu) using the *Concept Sheet Submittal Form* (http://statepiaps.jhsph.edu/wihs/admin/forms-investigator/forms-investigator.htm). CS submitted with incomplete or outdated submittal forms will be returned to the author for correction before posting.

Before submission to WDMAC, it is recommended that concepts be discussed with appropriate Working Group members, Principal Investigators and/or Project Directors to evaluate the science and assess the feasibility of the study. Investigators are requested to provide a timeframe for completion of proposals. It may be difficult to determine the timeframe for proposals that involve collection of new specimens or data (i.e., new protocols). The timeframe will depend on the timing of protocol implementation and/or the availability of data and specimens. The investigator should consider these issues when filling out the "date manuscript will be completed" field on the *Concept Sheet Submission Form* and provide a tentative but realistic completion date since this is tracked by the EC.

When a CS is received by WDMAC, WDMAC will fill out an internal checklist, assign reviewers, and determine whether or not the proposed project contains high priority science.

1. REGULAR REVIEW CONCEPT SHEETS

To ensure that all potential projects receive critical evaluation, WDMAC will assign specific reviewers from the below list, as necessary. (See **Appendix C** for a list of potential reviewers.)

- Principal Investigator Reviewer (PIR), from among the SCC members, will be asked to review each CS in detail (assignments made on a rotating basis). The PIR should review all posted comments before giving a final approval rating for a CS.
- Project Director Reviewer (PDR), from among the six clinical sites, will be assigned to review a CS if it will require the collection of new data or new specimens, or if its implementation will impact clinic operations.
- Lab Reviewer (LR) will be assigned to review a CS if any new specimens will be collected from participants, or if specimens will be withdrawn from any WIHS central repository (i.e., SeraCare, Fisher, DNA).
- Genetics Reviewer (GR) will be assigned to review a CS if DNA is being requested from the WIHS DNA Repository, if specimens from SeraCare or Fisher will be used by the investigator to create his/her own genetic materials for study, or if any genetics analysis is to be done as part of the concept sheet.

If the CS requires regular, non-high-priority review, WDMAC will notify all EC and Scientific Chairs Committee (SCC) members via e-mail that a concept has been posted to the WIHS Forum (http://statepiaps2.jhsph.edu/WIHS_forum/index.php). During a two-week review period, all EC and SCC members, as well as PDR, LR and GR, will have the opportunity to post comments about the CS to the WIHS Forum.

At the end of the two-week period, the PIR will post the results of the review along with his/her ultimate recommendation for approval or rejection. PIRs should consider comments made by others, the significance of and need for the proposed investigation, whether the project overlaps with other ongoing or submitted proposals, and whether the science is relevant to WIHS. If there is overlap with existing projects, then the PIR must indicate if the project should be combined with other related projects or revised to avoid overlap. The PIR will determine if the CS is approved as is, approved with comment, approved with major revision, or rejected.

If the CS was submitted by an external investigator, it is the responsibility of the PIR to assign a WIHS collaborator to work with the investigator. The PIR will list the name of the suggested WIHS collaborator on the CS Review form. WDMAC will then post the name of the assigned collaborator to the WIHS Forum.

If, after review, the PIR thinks additional discussion is necessary for a given CS, then the project can be discussed on the next scheduled EC-Admin or SCC conference call, depending upon whether the needed review is scientific (e.g., questions related to: is science relevant to WIHS, should project be high priority, etc., would be discussed on SCC call), or operational (e.g., questions regarding implementation, overlap, etc., would be discussed on EC-Admin call).

Furthermore, projects requiring collection of new data or modifications to existing data collection instruments or methods will be only provisionally approved until they can be reviewed in detail by the EC and SCC at the time of planning for study visits, twice per year, usually in January for the visit beginning April 1, and in July for the visit beginning October 1.

2. **HIGH-PRIORITY CONCEPT SHEETS**

If a CS is deemed high-priority, the CS will be forwarded to the SCC Chair and/or Co-chair for PIR review, and added as an agenda item on the next SCC conference call for discussion, and approval or rejection. In these cases, SCC members will act as the PIR. These CS will also be assigned a Project Director Reviewer, a Lab Reviewer and/or a Genetics Reviewer, as needed. If new data will be collected as part of the proposal, the concept will be only provisionally approved until the semi-annual WIHS protocol discussion, at which time it may receive final approval.

3. **SITE-SPECIFIC CONCEPT SHEETS**

Site-specific CS are those that propose to utilize and/or collect data from one site only. All site-specific CS are posted for review, but do not require a PIR, PDR, LR or GR, unless central WIHS resources (e.g., funding, repository specimens, WDMAC analysis time, etc.) will be used. The Principal Investigator of the proposed study site only must post approval, and then the project can proceed. Site-specific CS will not be assigned co-authors from all sites.

4. **REVISED CONCEPT SHEETS**

Often investigators with a previously-approved CS wish to amend a CS to request additional specimens and/or data. In this case, the original CS Submittal Form should be revised. The investigator should highlight all changes and additions in another color to offset them from the original language. The lay language summary should also be revised accordingly. In all cases possible, the original PIR, PDR, LR and/or GR should be assigned for review of the revised CS. Revised CS that are approved will either (1) be assigned the same README number as the original project, if the amendment requests additional resources solely for completion of the

initial project, or (2) be assigned a new README number if the amendment proposes the addition of data/analyses to the project that will result in publication of an additional manuscript.

5. **NIH GRANT SUBMISSIONS**

   If an investigator plans to submit his/her concept sheet to the National Institutes of Health (NIH) as part of a grant submission (e.g., R01, R23), the concept sheet will not undergo a typical WIHS review. The WIHS will accept the NIH judgement as to the scientific merit of the work and will not require a separate PIR in order to judge the scientific merit of the proposal. A PIR will be assigned, however, to complete an administrative review of the concept sheet. This will include looking for overlap with already approved work in the WIHS and commenting on specimen and data availability. These concept sheets will also be assigned a Project Director Reviewer, a Lab Reviewer and/or a Genetics Reviewer, as needed.

   If the NIH decides to fund the project, no further reviews will be needed by the WIHS. If the NIH decides not to fund the project, however, and the investigator still wishes to proceed with the work, then the concept sheet will be assigned a full PIR to judge the scientific merit of the work.

When the PIR has posted his or her comments and/or approval of a project, the submitting investigator(s) will be notified by WDMAC within one week that the CS has been accepted, accepted with revision, or rejected. If the investigator(s) does not have access to the WIHS Forum, he or she will receive PIR (and other) comments via email from WDMAC. If a revision is requested, the investigator is responsible for sending WDMAC an updated version of the CS. After revisions are received, the CS will be reposted and assigned a one-week re-review period. The same PIR (and PDR, LR and GR, as appropriate) will be responsible for reviewing the revised proposal.

For both regular and high-priority CS, once a final decision is made, WDMAC will send a letter of project approval or rejection to the lead investigator within one week of the decision. If the approved CS is WIHS wide, WDMAC will then solicit for co-authors from all WIHS sites. Sites are required to post their proposed co-authors to the WIHS Forum within two weeks. If a site does not post a co-author in this timeframe, the site's PI will be assigned as the co-author on the project. Please visit the following link for a list of project co-authors since 2007: http://statepiaps.jhsph.edu/wihs/admin/concept-sheet-info/coauthor-database.htm.

WDMAC will assign all EC-approved CS a README number and will track the project using this number for all manuscripts and other projects that ensue.

Please note that the special process for review of high-priority CS by the SCC was added with the WIHS IV implementation of the Scientific Chairs Committee. Please see **Appendix B** for a breakdown of the levels of concept sheet review.

B. CREDIT, AUTHORSHIP, AND WRITING COMMITTEES

The following categories specify how credit and authorship is apportioned for most WIHS projects. Special requests are discussed and voted upon by the WIHS Executive Committee.

All manuscripts from approved projects are required to receive EC and/or SCC review (**Section D** below). Furthermore, all WIHS manuscripts must acknowledge that the data were collected through the Women's Interagency HIV Study. They must also credit participating institutions (WIHS representatives, plus WDMAC and the supporting NIH agencies) and grant numbers. **Appendix A** contains examples of both short and long format WIHS acknowledgments.

All investigators must acknowledge that WIHS specimens and data are the property of WIHS. Investigators are responsible for reviewing and agreeing to the WIHS Publication Policy, ensuring that the samples and data are used in the manner outlined in the concept sheet, and disseminating results to assigned WIHS collaborators/co-authors in a timely manner.

If an investigator later wishes to change the study methods or to expand the scope of an already-approved project, then an amendment to the CS must be submitted for review by the WIHS EC. (See **Section A4**, above.)

1. SINGLE-SITE INVESTIGATIONS

A single-site investigation is one using data collected from one site only and funded through that site's WIHS collaborative agreement or external sources (e.g., RO1, GCRC, unobligated funds, etc.). These data may be collected as part of a pilot study, the core WIHS protocol, a local substudy, or generated from local specimens collected during WIHS or additional visits. In general, single-site investigations should be rare; investigators are encouraged to utilize the entire WIHS cohort for most projects.

Publications resulting from single-site investigations will include co-authors and other authors at the discretion of the lead investigator from the local site. Manuscripts should be approved by the site Principal Investigator prior to submission to the WIHS Executive Committee for final review.

2. CORE INVESTIGATIONS

A core investigation is one using data generated as part of the seven principal WIHS collaborative agreements (i.e., six clinical sites and WDMAC). These data may be part of the core WIHS protocol, a substudy, or generated from specimens collected as part of WIHS visits. Funding may come from the core collaborative agreement, supplements, RO1s or re-apportionment of unobligated funds.

The lead investigator of a core investigation does not necessarily need to be supported by WIHS (i.e., can be an "external" investigator). However, the WIHS reserves the right to assign a new lead author to a project if an external investigator does not wish to write up the study results but agrees that a publication is worthwhile.

While WDMAC performs the analyses for many core investigations, data analyses may be conducted elsewhere for both core and external projects. In these cases, the lead investigator should arrange for WDMAC to receive data sets and programs that relate to the tables and figures in the manuscript upon publication.

In some cases, analyses will utilize data from a subset of all six clinical sites. For these investigations, site representation will be solicited only from the sites contributing data and/or analytic support.

a. Authorship for Projects Led by WIHS Investigator

Core investigations led by a WIHS investigator require that each of the seven Principal Investigators (including WDMAC, even if the analysis is conducted elsewhere) be offered co-author representation in recognition of the substantial amount of operational work performed by each site for cohort recruitment, retention, data collection, and data management. After approval of the CS, WDMAC will email the seven Principal Investigators to request assignment of co-authors. Failure to name a co-author within two weeks will result in the site having the Principal Investigator serve as the co-author by default.

b. Authorship for Projects Led by "External" Investigator

Core investigations led by an external investigator also require that each of the seven Principal Investigators (including WDMAC, even if the analysis is conducted elsewhere) be offered co-author representation. The process for assigning co-authors is the same as the process for core investigations led by WIHS investigators. After all co-authors have been assigned, WDMAC will contact the external investigator with the names and email addresses for each site representative.

In addition, the lead investigator on a project should include as a co-author any investigators and

analysts (WIHS or external) that make substantial contributions to the project. The WIHS adheres to criteria for authorship promulgated by the International Committee of Medical Journal Editors (http://www.icmje.org/).

3. NESTED INVESTIGATIONS COLLECTING NEW DATA

WIHS funding through the seven principal collaborative agreements is limited and is necessary to support the core study protocol and scientific priorities of the WIHS Executive Committee. Thus, it is expected that many studies generating new data will be supported with external funds. These may include data obtained directly from participants outside of the core WIHS protocol (e.g., during interim substudy visits), specimen collection, utilization of specimens from the central WIHS repositories, or data generated using central repository specimens. Nested investigations may be initiated by individuals supported or not supported on core WIHS collaborative agreements (including WIHS Principal Investigators).

In general, the co-authorship guidelines for nested investigations will follow those for single-site or core investigations. Project investigators have a right to utilize and publish new data generated from external funding sources prior to sharing with other WIHS investigators. However, once the aims of the CS have been completed and published, the new data must be transmitted to WDMAC for integration with the core WIHS database and release to other WIHS investigators.

4. MULTI-COHORT COLLABORATIVE INVESTIGATIONS

Proposed studies that involve pooled data from WIHS and other cohorts should include authors from each of the partner organizations involved. It is recognized that multi-cohort collaborations can result in an unwieldy number of co-authors. Hence, in general, only one or two WIHS representatives will be assigned to multi-cohort collaborations, in addition to the project investigators. WDMAC should contact a WIHS SCC member with expertise in the area of investigation for help in selecting a WIHS co-author(s) for these projects.

In some cases, the WIHS is involved in multi-region collaborations as part of NA-ACCORD and IeDEA. Due to the large number of possible co-authors for these collaborations, the WIHS may not always be granted the opportunity to be represented as a co-author.

5. METHODOLOGICAL INVESTIGATIONS

Investigators may propose statistical or laboratory methodological projects that utilize data or specimens collected as part of the core WIHS from multiple sites. The primary aim of these projects is the development or adaptation of new statistical or laboratory methods, with limited substantive results. Most of these projects are targeted towards publication in specialty journals. At the time the CS is submitted, the lead investigators may petition the WIHS Executive Committee to ask that these projects receive, at most, a single WIHS representative for the paper.

C. REQUESTS FOR DATA, SPECIMENS, AND ANALYTIC SUPPORT

Once a project is approved, and if analysis is to be performed by WDMAC, the lead investigator should communicate with WDMAC to start collaboration on study design, creation of analytical datasets, and selection of repository specimens and data analysis.

1. DATA REQUESTS

Data requests are fulfilled mainly for external investigators, as WIHS investigators already have access to the entire WIHS data set, which is distributed semiannually on CD to all site Data Managers. All data requests that cannot be filled at the local level should be submitted to the WDMAC Project Director via e-mail (Christine Alden, calden@jhsph.edu). The e-mail should include a list of WIHS variable names and the corresponding form number needed for the dataset, as well as the visit number(s) and/or calendar dates for which data are needed. Variable names can be obtained from the WIHS codebooks. Codebooks are distributed on data freezes to the Data

Managers at each site and are also located on the WIHS Administrative Web site (http://statepiaps.jhsph.edu/wihs/admin/codebooks/codebooks.html). A WDMAC programmer will be assigned to the project once a data request is made. WDMAC requires a two-week time period for the production of an analytic database. If the data request is complex, additional time may be necessary.

2. SPECIMEN REQUESTS

All specimen requests should be submitted to the WDMAC Project Director via e-mail or fax (Christine Alden, calden@jhsph.edu, fax: 410-223-1666). Requests for specimens will not be processed until verification of local IRB approval has been provided. Investigators should consult the **WIHS Manual of Operations (MOO), Section 31,** prior to submitting a repository request. All requests should include a completed ***Central Repository Request Checklist*** (for requests from SeraCare or Fisher) or a completed ***DNA Biorepository Sample Request Form*** (for requests from the WIHS DNA repository) – both can be found at the following address: http://statepiaps.jhsph.edu/wihs/index-invest-info.htm.

a. Selection of Specimens

If an investigator has already determined the appropriate WIHSID-visits for his/her project, an Excel spreadsheet of WIHSIDs, visits and visit dates should be attached to the e-mailed specimen request. If the investigator has not yet determined appropriate WIHSID-visits, a WDMAC programmer will be assigned to work with the investigator to select appropriate WIHSID-visits based on the selection criteria in the approved concept sheet.

b. WIHS Specimen Allocation Committee Review

The WIHS Specimen Allocation Committee (WSAC) was formed in 2009 and charged by the WIHS EC to assist in the allocation of high-value WIHS repository specimens. The WSAC reviews all requests for the release of samples from individuals who contribute significant or unique outcomes to overall WIHS research aims and to determine whether or not the restricted samples should be released to the requesting investigator. When necessary, the WSAC may be asked to review concept sheets that request the use of high-value samples.

Restricted specimens include those from:

- *HIV seroconverters:* last three negative visits, plus all positive visits
- *Pre-HAART deaths:* all visits for women who died during WIHS I (i.e., on or before September 30, 1997) with at least two years of follow up
- *HAART initiators* (i.e., ART-naïve women who initiated HAART): one visit before HAART initiation, plus first three visits after HAART initiation (i.e., first reported HAART visit, plus the two visits subsequent to initiation)
- *Long-term non-progressors:* all visits
- *Elite non-progressors:* all visits
- *Incident cancers:* up to four pre-cancer visits, plus the visit at which the cancer is reported
- *Hormonal birth control users:* all visits from both HIV-positive and HIV-negative participants

Once WDMAC has identified the WIHSID/visits for a particular request, investigators may elect to drop restricted person-visits and proceed without these samples. Alternatively, investigators may ask for a WSAC review of their request to use these specimens. The WSAC will converse either by email or conference call to determine

whether the scientific value of the concept sheet merits inclusion of the restricted specimens in the request.

WDMAC will facilitate this process by tracking requests in a database and sending an email notification including the following information:

- Investigator name, title of concept sheet, readme number, and links to concept sheet and original forum review
- Short summary of the request: selection criteria, specimen type, aliquot number and total volume needed for testing, tests to be performed, expected person-visits, expected number of samples
- Summary of restricted person-visits: percent restricted person-visits in request, if alternate person-visits are possible, summary of reasons for requesting the restricted person-visits as they relate to the aims/hypotheses of the concept sheet, number of specimens current available and how the request would deplete the person-visits available
- Other extenuating circumstances known by the coordinator

Once they have received the notification, WSAC members will have one week to respond as to whether or not they approve the use of restricted samples. After responses have been received by WDMAC, the coordinator will complete the WIHS Specimen Allocation Committee (WSAC) Review Form, send a copy to the requesting investigator, and post the review to the original concept sheet review. If the WSAC does not approve the use of restricted specimens, the requesting investigator can appeal to the WIHS EC.

D. MANUSCRIPTS AND ABSTRACTS

1. REVIEW OF MANUSCRIPTS

Full EC review is mandatory for all manuscripts, including site-specific manuscripts and manuscripts lead by an external investigator. Co-author(s) must participate in the writing and/or review process in a timely manner. If a co-author does not participate, he or she may be removed from the manuscript at the discretion of the EC. The lead investigator should circulate a draft copy of the manuscript amongst all co-authors and incorporate co-author comments. Once the manuscript has been approved by all co-authors, the lead investigator should submit it electronically to WDMAC (wdmac@jhsph.edu) using the *Manuscript Submittal Form* (http://statepiaps.jhsph.edu/wihs/admin/forms-investigator/forms-investigator.htm). Manuscripts submitted with incomplete or outdated submittal forms will be returned to the author for correction before posting.

If a co-author disagrees with the main findings or methods of a manuscript, or finds the data or analysis misleading, he/she must resolve these issues with the writing group/co-authors before the manuscript is submitted to the EC. If a co-author still finds fault with the version submitted to the EC, he or she should address these concerns with the lead investigator. The co-author may also indicate his or her concerns by posting to the manuscript thread in the WIHS Forum. If one or more of the co-authors still disagree with the lead author regarding analyses in the paper, he or she may wish to be removed as a co-author. This should be done before submission for EC review.

Once the manuscript has been submitted, WDMAC will assign a PI Reviewer (PIR) who is: neither (1) a co-author nor (2) the PI from the first author's WIHS site. A two-week deadline will be established for the PIR to review the manuscript.

WDMAC will post the manuscript to the WIHS Forum and notify the PIR, SCC members, EC members, and co-authors via email about the posting and review deadline. All co-authors must

post their approval to the Forum. In addition, all WIHS investigators, not just the PIR, are encouraged to post comments to the Forum by the stated deadline. The PIR will review the manuscript and co-authors' and EC/SCC members' comments and complete the *Manuscript Review Form* (http://statepiaps.jhsph.edu/wihs/admin/forms-investigator/forms-investigator.htm) by the end of the two-week review deadline. The PIR can chose to either (1) approve, or (2) not approve and request revisions to the manuscript.

If the manuscript is "approved," the PIR may suggest revisions, but the lead investigator is not required to implement them prior to journal submission. If the PIR does not post a review by the two-week deadline, the manuscript will be automatically approved for journal submission.

If the manuscript is "not approved" (i.e., revision is required), the lead investigator must revise and resubmit the manuscript to WDMAC so that it can be posted and re-reviewed by the PIR. If the lead investigator does not feel the requirement for revision is warranted, or does not agree with the suggested revisions, the author may appeal to the SCC. Also if the resubmitted manuscript is again not approved by the PIR, the author may appeal to the SCC. If the author decides to appeal the PIR's decision, discussion of the manuscript will be added to the agenda for the next scheduled SCC call.

2. REVIEW OF ABSTRACTS AND PRESENTATIONS

Final abstracts and presentations must adhere to the following guidelines:

- Abstracts must be associated with an EC-approved concept sheet.
- Co-authors should be the same as the ones assigned for the EC-approved concept sheet. If an investigator needs the list of assigned co-authors, he/she can contact WDMAC at wdmac@jhsph.edu.
- WIHS-wide abstracts require co-authors from each WIHS site. WIHS collaborations (multi-cohort projects) require one co-author representative from the WIHS.
- Abstracts must be provided to co-authors before the abstract is submitted to WDMAC for EC review and approval. Co-authors must be given at least three business days to review and approve the abstract before it is submitted to WDMAC for EC review and approval. The submitting investigator should indicate upon submittal to WDMAC that co-authors were provided three business days to review and approve.
- If a co-author does not respond within that three business day period, the submitting investigator can assume approval and proceed with submission to WDMAC for EC review and approval. If a co-author wishes to be removed from the abstract, the submitting investigator should indicate this upon submittal to WDMAC.
- EC approval is needed for abstracts prior to submittal to a scientific meeting/conference. Abstracts must be submitted to WDMAC (with co-author approval) at least five business days prior to the scientific meeting/conference submission deadline.

If the aforementioned guidelines are not met, the following policy will take effect:

- If an abstract is submitted to WDMAC without co-author approval, the abstract will be returned to the lead investigator for circulation to all co-authors for review and approval. The abstract will not be distributed to EC members until all of the above requirements have been met.
- If three business days are not provided to co-authors to review and approve the abstract before the scientific meeting/conference submission deadline, the abstract will not be EC-approved and cannot be submitted to the scientific meeting/conference.
- If an abstract is submitted to WDMAC with co-author approval but five business days are not provided for the EC to review and approve, the investigator will be permitted to submit to the scientific meeting/conference with the permission of his/her site Principal Investigator. If, after the five business day EC review period, the EC does not approve of

the abstract, the investigator will be required to withdraw the abstract from the scientific meeting/conference.

If the abstract is being submitted to a conference that limits the number of abstracts that can be submitted from any one cohort, the following abstract submission policy will take effect:

- All abstracts must be submitted to co-authors for review and approval three business days before submitting for EC review.
- All co-author approved abstracts must be submitted for EC review at least 72 hours (three business days) before the abstract submission deadline.
- Abstracts that are submitted without 72 hours remaining before the abstract submission deadline will not be approved for submission.
- After all compliant abstracts have been received, they will be distributed to EC/SCC members and members will be asked to apply a forced ranking system to rank the top six [or the number set by the conference] abstracts.
- Investigators from the top abstracts will be notified that they can submit to the conference. All others will be informed that their abstract was not approved for submission.
- All other abstracts submission guidelines apply.

Investigators must email their proposed abstract to WDMAC at wdmac@jhsph.edu. The following information must be included with the submission: name and dates of conference, conference abstract submission deadline, abstract title, REAMDE#, list of co-authors, and a copy of the abstract. Abstracts will be posted to the WIHS Forum. WIHS EC members will be notified of the posting via e-mail and will have one week to comment on the abstract, and recommend acceptance, acceptance with revisions, or rejection. All co-authors must review and approve the final EC-approved abstract before presentation. If the abstract is the result of a site-specific study, the abstract will still be posted to the WIHS Forum and WIHS EC members will be notified of the posting via e-mail. However, site-specific abstracts only require the approval of the site PI prior to submittal to a meeting/conference.

3. JOURNAL SUBMISSION

The lead investigator must notify WDMAC electronically (wdmac@jhsph.edu), using the *Publication Submission Form* (http://statepiaps.jhsph.edu/wihs/forms/pub-sub-form.html), whenever a manuscript is submitted to a journal. After a journal has reviewed the manuscript, the lead investigator should update the *Publication Submission Form* and resend to WDMAC. This form helps WDMAC track all WIHS publications and ensures publications are properly archived and listed in the publication list. If a manuscript is accepted for publication, lead authors are also responsible for sending a PDF (Portable Document Format) version of the published article to WDMAC (wdmac@jhsph.edu).

Please remember that presentations or manuscript submissions that do not have prior EC approval and NIH notification are inconsistent with the spirit of collaborative research. Disregard of this policy may result in future denial of access to WIHS data and a cessation of collaborative support. In addition, presentation or submission of unapproved manuscripts puts the investigator at risk of disciplinary proceedings by the WIHS EC and/or funding agencies.

Publications and presentations shall be in compliance with the rules and procedures of the disclosure set forth in the Privacy Act. Confidential or proprietary information shall not be disclosed without the prior written consent of the individual or institution. Privacy Act compliance and documentation of written disclosure consents are the responsibility of each institution involved in the paper/presentation.

4. SUBMISSION OF MANUSCRIPTS TO NIH

NIH requires all WIHS investigators who are participating in this study, which is funded by NIH, to make their peer-reviewed final manuscripts available to other researchers and to the public at the National Library of Medicine's (NLM) PubMed Central (PMC) (http://www.pubmedcentral.nih.gov) within 12 months of the publication date. NIH expects investigators to submit an electronic copy of the final version of the manuscript accepted for publication. A separate submission is not necessary if the manuscript has been accepted by a journal that permits free access to PDFs within 12 months of publication. (These journals are listed at the above web site.) To submit PDFs of articles please visit the NIHMS system web site: (http://www.nihms.nih.gov).

E. SLIDE PRESENTATIONS

Subsequent to each WIHS or joint WIHS/MACS Executive Committee Meeting, PDF versions of all slide presentations will be posted to the WIHS Administrative web site: http://statepiaps.jhsph.edu/wihs/admin/presentations/presentations.htm. A password is required to access this site. Slides from these presentations may not be copied or distributed without permission from the author.

II. PUBLICITY POLICY

A. LOCAL PUBLICITY

Local publicity refers to media distributed to each site's city, metropolitan area, or state. This includes local TV stations, radio stations, and newspapers; city, county, or state health department newsletters; hospital publications; and local university publications, not available by general public subscription.

1. Each site may release general information about their site and about the WIHS to local media.
2. Study data, other than that included in the *WIHS Dossier*, or published analyses should never be disclosed without prior clearance by the EC.

B. REGIONAL/NATIONAL PUBLICITY

National publicity refers to media distributed widely outside each site's city, metropolitan area, or state. This includes network television, network radio, major newspapers, national newsletters and widely disseminated university publications.

Because national publicity may impact the overall reputation of the WIHS, all questions by national media should be directed to the site's Principal Investigator, who should then notify cooperating federal agencies.

WIHS data analyses should never be discussed without prior clearance by the WIHS EC. Media questions about the WIHS should always be directed to WIHS Principal Investigators and/or cooperating federal agencies.

C. GENERAL GUIDELINES

1. If significant questions arise about WIHS sites or funding agencies (e.g., "How much is XX agency spending overall on the WIHS study?"), refer the reporter to the appropriate agency (i.e., investigators at those sites or agencies).
2. When answering questions, make clear distinctions between personal opinions and positions that have been arrived at jointly by the WIHS collaborators.

Appendix A – WIHS Acknowledgments

SHORT FORM:

Data in this manuscript were collected by the Women's Interagency HIV Study (WIHS) Collaborative Study Group with centers (Principal Investigators) at New York City/Bronx Consortium (Kathryn Anastos); Brooklyn, NY (Howard Minkoff); Washington, DC, Metropolitan Consortium (Mary Young); The Connie Wofsy Study Consortium of Northern California (Ruth Greenblatt); Los Angeles County/Southern California Consortium (Alexandra Levine); Chicago Consortium (Mardge Cohen); Data Coordinating Center (Stephen Gange). The WIHS is funded by the National Institute of Allergy and Infectious Diseases (UO1-AI-35004, UO1-AI-31834, UO1-AI-34994, UO1-AI-34989, UO1-AI-34993, and UO1-AI-42590) and by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (UO1-HD-32632). The study is co-funded by the National Cancer Institute, the National Institute on Drug Abuse, and the National Institute on Deafness and Other Communication Disorders. Funding is also provided by the National Center for Research Resources (UCSF-CTSI Grant Number UL1 RR024131). The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of the National Institutes of Health.

LONG FORM:

The Women's Interagency HIV Study (WIHS) Collaborative Study Group includes the following:

New York City/Bronx Consortium:
Montefiore Medical Center (**Kathryn Anastos, MD (Principal Investigator)**; Anthony Cajigas, MD; Esther Robison, PhD; Rodney Wright, MD); University of California Davis (Harold Burger, MD, PhD; Barbara Weiser, MD); Albert Einstein College of Medicine (Robert Kaplan, PhD; Marla Keller, MD); Weill Medical College of Cornell University (Marshall Glesby, MD); Rutgers (Don Hoover, PhD); Community Advisor (Nilsa Ramos-Santiago).

Brooklyn, NY:
State University of New York Health Science Center at Brooklyn (**Howard Minkoff, MD (Principal Investigator)**; **Deborah Gustafson, PhD (Co-Principal Investigator)**; Michael Augenbraun, MD; Howard Crystal, MD; Jack DeHovitz, MD, MPH; Helen Durkin, PhD; Susan Holman, RN, MS; Jason Lazar, MD; Maja Nowakowski, PhD; Rebecca Schwartz, PhD; David Seifer, MD; Anjali Sharma, MD, MS; Tracey Wilson, PhD).

Washington, DC, Metropolitan Consortium:
Georgetown University Medical Center (**Mary Young, MD (Principal Investigator);** Lakshmi Goparaju, PhD); George Washington University Medical Center (Sylvia Silver, DA); Whitman-Walker Clinic (Kunthavi Sathasivam, MD); Montgomery County Health Department (Carol Jordan, RN, MPH); Inova Health System of Northern Virginia (David Wheeler, MD; Barbara Lawrence, BS); Community Advisors (Kimberley Kelsey, Kathy Moore).

The Connie Wofsy Study Consortium of Northern California:
University of California, San Francisco (**Ruth Greenblatt, MD (Principal Investigator)**; Peter Bacchetti, PhD; Deborah Cohan, MD, MPH; Nancy Hessol, MSPH; Phyllis Tien, MD); Alameda County Medical Center (Howard Edelstein, MD); Alta Bates Medical Center (Claire Borkert, MD); Community Advisor (Nilda Rodriguez).

Los Angeles County/Southern California Consortium:
Keck School of Medicine, University of Southern California and Los Angeles County & USC Medical Center (**Alexandra M. Levine, MD (Principal Investigator)**; Yvonne Barranday, BA; Marek Nowicki, PhD; Leigh Pearce, PhD; Jean Richardson, DrPH); the Santa Barbara County Department of Health Services (Elizabeth Downing, MD); University of Hawaii (Cecilia Shikuma, MD); Community Advisor (Elisa Sanchez).

Chicago Consortium:
Cook County Hospital **(Mardge H. Cohen, MD (Principal Investigator)**; Audrey French, MD; Kathleen M. Weber, BSN); University of Illinois at Chicago (Ronald Hershow, MD); Rush Presbyterian-St. Luke's Medical Center (Beverly Sha, MD); Northwestern Memorial Hospital (Sarah Sutton, MD); Community Advisor (Marta Santiago).

Data Coordinating Center:
Johns Hopkins Bloomberg School of Public Health **(Stephen Gange, PhD (Principal Investigator)**; **Elizabeth Golub, PhD, MPH (Co-Principal Investigator)**; Alison Abraham, PhD; Christine Alden, BA; Keri Althoff, PhD, MPH; Lorie Benning, MS; Christopher Cox, PhD; Gypsyamber D'Souza, PhD; Lisa Jacobson, ScD; Bryan Lau, PhD; Sharada Modur, PhD; Alvaro Muñoz, PhD; Christopher Pierce, MHS; Aaron Platt, BS; Michael Schneider, MS; Eric Seaberg, PhD, MPH; Gayle Springer, MLA; Sol Su, ScD; Eryka Wentz, MA; Won Yoo, BS; Jinbing Zhang, MS).

NIH:
National Institute of Allergy and Infectious Diseases (Gerald Sharp, DrPH; Carolyn Williams, PhD); *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (Kevin Ryan, PhD; Heather Watts, MD); National Institute of Drug Abuse (Katherine Davenny, MPH; Richard Jenkins, PhD); National Cancer Institute (Geraldina Dominguez, PhD).

WIHS Oral Substudy Acknowledgment Format

LONG FORM:

The Oral Substudy of the Women's Interagency HIV Study (WIHS) Collaborative Study Group includes the following:

- ***New York City/Bronx Consortium:*** NYU School of Dentistry, New York, NY.
- ***The Connie Wofsy Study Consortium of Northern California:*** University of California, San Francisco (Deborah Greenspan, B.D.S., D.Sc. John S. Greenspan, B.D.S., Ph.D., F.R.C.Path.).
- ***Los Angeles County/Southern California Consortium:*** University of Southern California, Los Angeles (Roseann Mulligan, D.D.S., M.S.; Mahvash Navazesh, D.M.D.; Joyce Galligan, R.N., D.D.S.; Nancy Kiehl-Hillman, R.D.H., M.S.; Kristi Ellis, R.D.H.).
- ***Chicago Consortium:*** University of Illinois at Chicago (Mario Alves, D.D.S., M.S., D.Sc.).
- ***Data Coordinating Center:*** Johns Hopkins University Bloomberg School of Public Health, (Stephen J. Gange, Ph.D.).
- ***NIH:*** National Institute of Dental and Craniofacial Research (Dennis Mangan, Ph.D.).

SHORT FORM:

Data in this manuscript were collected by the Oral Substudy of the Women's Interagency HIV Study (WIHS) Collaborative Study Group with centers (Principal Investigators) at New York City/Bronx Consortium; The Connie Wofsy Study Consortium of Northern California (Deborah Greenspan, John S. Greenspan); Los Angeles County/Southern California Consortium (Roseann Mulligan, Mahvash Navazesh); Chicago Consortium (Mario Alves); Data Coordinating Center (Stephen Gange). The WIHS Oral Substudy is funded by the National Institute of Dental and Craniofacial Research.

Appendix B – Levels of Concept Sheet Review

- ***Level 1***: High-impact/high-priority concepts or those concepts requesting expedited review. Assigned for discussion among Scientific Chairs Committee members, via conference call or email. The SCC Chair or Co-chair will serve as the "PI Reviewer" and will formulate the recommendation of the Scientific Chairs Committee (i.e., reject, revise/get more info, approve with comment, approve). When necessary, level 1 concept sheets will also be assigned a Project Director Reviewer, a Lab Reviewer and/or a Genetics Reviewer. If collection of new data and/or specimens is required, these concepts will receive only provisional approval until review on the semiannual WIHS protocol discussion (in January and July) when final approval is determined.
- ***Level 2***: Minimally invasive, analysis of existing data only. Assigned PI Reviewer only. Concept sheet submission notification sent out to all SCC and EC members. Forum is available for comments – PI Reviewer makes comments and final decision.
- ***Level 3***: Requires use of existing data and specimens. Assigned PI Reviewer, Lab Reviewer, Genetics Reviewer (if genetic analysis), and any other relevant Working Group chairs as deemed necessary. Process as with Level 2, but requires all assigned reviewers to approve.
- ***Level 4***: Requires new data / specimen collection but not high priority. Assigned PIR, PDR and LR and/or GR, if needed, and any other Working Group chairs as deemed necessary. If collection of new data and/or specimens is required, these concepts will receive only provisional approval until review on the semiannual WIHS protocol discussion (in January and July) when final approval is determined (unless mechanisms for a separate visit are proposed independent of the core).

Appendix C – Available Concept Sheet and Manuscript Reviewers (area of expertise)

SCC REVEIWERS (PIR)

Kathy Anastos (epidemiology, metabolic, general)

Howard Minkoff (HPV, menopause/reproductive issues, epidemiology, general)

Mary Young (neurocognition, epidemiology, general)

Alexandra Levine (cancer/pathology, epidemiology, general)

Ruth Greenblatt (epidemiology, menopause/reproductive issues, genetics, pharmacokinetics, metabolics, general)

Mardge Cohen (behavior, epidemiology, general)

Alan Landay (virology, immunology, pathogenesis)

Phyllis Tien (epidemiology, hepatitis/liver, metabolics, CVD)

Robert Kaplan (CVD, metabolics)

Marion Peters (liver/hepatitis)

Audrey French (epidemiology, liver/hepatitis)

Pauline Maki (neurocognition, menopause/reproductive issues)

Tracey Wilson (behavior)

Howard Strickler (HPV, liver/hepatitis)

Nancy Hessol (cancer/pathology, epidemiology)

Brad Aouizerat (genetics)

Stephen Gange (statistical methodology, epidemiology)

Elizabeth Golub (epidemiology)

Deborah Gustafson (metabolics, cognition, adiposity)

PROJECT DIRECTOR REVIEWERS (PDR)

Esther Robison

Susan Holman

Lakshmi Goparaju

Yvonne Barranday

Claudia Ponath

Kathleen Weber

LAB REVIEWERS (LR)

Marek Nowicki (virology, cellular immunology, serology)

Bill Meyer (virology, immunology, clinical chemistry)

Maria Villacres (cellular immunology, serology)

Yvonne DeSouza (immunology, cell culture)

Seema Desai (cellular immunology)

Alan Hiti (clinical chemistry, serology)

Zhang Jinbing (molecular biology)

Carl Hanson (serology, immunology, virology)

GENETICS REVIEWERS (GR)

Brad Aouizerat (genetics)