WOMEN'S INTERAGENCY HIV STUDY
SECTION 3: CONCEPT SHEET & PUBLICATION/PUBLICITY POLICY

A standardized research concept submission and 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; therefore, all investigators who wish to use and publish data from the WIHS **MUST** follow the policy below.

I. CONCEPT SHEETS (CS)

Submission of a study protocol in the form of a concept sheet (CS) 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.

A. CONCEPT SHEET DEVELOPMENT

Submitted concept sheets are evaluated for relevance to WIHS core aims and hypotheses and to determine if there is duplication with other WIHS initiatives. A clear, practical and focused proposal is necessary for the Executive Committee (EC) to adequately evaluate the success of a protocol.

As an initial step in the development of a concept sheet, investigator(s) should carefully evaluate the aims of WIHS, review the ongoing research studies and craft a concept that is feasible and does not overlap with the existing WIHS scientific agenda.

1. CONCEPT SHEET DEVELOPMENT

Investigator(s) should work closely with their site PI or WIHS liaison in the development of a draft concept sheet.

NOTE: If you are an external investigator and do not have a WIHS liaison, contact WDMAC (jhsph.wdmac@jhu.edu) for assistance with identifying one.

Investigators should consider, and address, the following questions in their concept sheet proposal.

- What are the specific aims of this investigation and how do they complement the WIHS scientific aims (found in MOO, Section 1).
  - Is there overlap with any existing concepts?
- What data/specimens will be used or collected?
  - What sites and participants will be eligible?
  - If additional data or specimens are to be collected:
    - At what point in the study visit will the additional data collection take place?
    - What test/analysis will be performed?

- How will specimens be tested, and by whom?
- Will the results be provided to participants?

- What are the logistical considerations?
  - Is this concept part of a grant submission? If so, what is the timeline for submission?
  - Has the local IRB approved this study? Will new IRB approval or IRB amendments be needed from other sites?
- If additional data or specimens are to be collected:
  - How long will data/specimen collection take? Will a separate visit be needed?
  - What training or equipment/supplies will be needed in order to implement the protocol?
  - Who will provide training or equipment/supplies?
  - Will sites or participants be reimbursed for the additional effort? If so, what mechanism will be used to reimburse sites (e.g., fee for service, contract)?

2. PRE-SUBMISSION REVIEW

Investigator(s) must review the proposed research with either their site's PI (for internal investigators) or a WIHS liaison (for external investigators) prior to submitting the concept for EC review.

In addition, **if** the concept sheet includes additional data or specimen collection, investigator(s) must also review the proposed research with the local site Project Director (PD), as well as the PDs from all sites that are being asked to participate. Investigator(s) should contact the relevant sites through their site PD or WIHS Liaison and should provide each site with: (1) the draft concept, (2) any new forms or questionnaires proposed for administration, and (3) an associated budget (if applicable).

The PDs will review the concept and provide the investigator(s) with feedback regarding the feasibility of the concept as well as the potential site burden. PDs will also work with the investigator(s) to develop a budget based on standardized rates for data collection, administrative/staff effort, and protocol implementation.

NOTE: *Budget negotiations must be completed before the concept sheet may be approved. Investigator(s) are encouraged to contact the PD chair as early as possible (3 months) in the CS process to ensure that a budget is finalized prior to any grant submission deadlines.*

Once the site PI/PD/WIHS liaison have reviewed the CS, the investigator(s) may submit the final version to WDMAC (jhsph.wdmac@jhu.edu). If the proposed research includes the collection of new data or specimens, investigator(s) must also submit the data collection instrument and a draft budget (if applicable).

Concept sheets that are submitted to WIHS prior to receiving approval from either the corresponding site PI or the WIHS liaison will not be reviewed by the WIHS EC.

B. CONCEPT SHEET REVIEW

Once the concept sheet has been submitted to WDMAC, it will be assigned the requisite reviewer(s) and posted to the WIHS Forum. Depending on the scope of the proposed concept, different levels of review may be necessary:

1. MULTI-SITE INVESTIGATIONS THAT PROPOSE NEW FORMS OR SPECIMEN COLLECTION

WIHS-wide concepts requiring new forms or specimen collection will be posted for review and assigned a Principal Investigator Reviewer (PIR); a Project Director Reviewer (PDR); 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), for all genomics studies. Once a concept sheet is posted, all reviewers other than the PIR are required to post their reviews within a 2-week (10-business-day) window. The PIR will be allotted two extra days to complete his/her review.

- **Principal Investigator Reviewer (PIR),** from among the site PIs and Working Group (WG) chairs, will be asked to review each CS in detail (assignments made on a rotating basis based on area of expertise). The PIR should review all posted comments before giving a final approval rating for a CS. The PIR will review the scientific merit, feasibility and potential overlap with other approved WIHS concepts.

  NOTE: The PIR will also review the CS for any potential conflicts of interest**.** Investigators are responsible for identifying financial interests that may create conflicts of interest or give the appearance of conflicts of interest. An investigator may hold a conflict of interest if they have significant financial or property interest in the outcomes of the WIHS research concept. This could include:

  - Investigators involved with developing or marketing a product or treatment that will be studied.
  - Investigators involved with developing or marketing a competing product or treatment.

  Investigators are required to disclose any conflict of interest on the CS submission form, as specified.

- The **Project Director Reviewer (PDR)** will review the feasibility and participant/staff burden of the proposed research activities. Investigator(s) should carefully address each of these issues within the concept sheet (see the Procedures for Implementation of Proposed New Protocols and Forms, MOO, Section 2, for further information). In addition, the PDR will include a review of the costs associated with the proposed research. All sub-studies that require data collection will need to ensure adequate WIHS site funding for activities (e.g., administrative/personnel effort, protocol administration, data management, participant reimbursement etc.).

- **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. To protect the most valuable and irreplaceable specimens in WIHS, central repository requests for specimens from certain groups of WIHS participants (HIV-seroconverter, ART-naïve HAART initiator, long-term non-progressor, elite non-progressor, incident cancer case, etc.) will receive additional review by the WIHS Specimen Allocation Committee (WSAC).
- **Genetics Reviewer (GR)** will be assigned to review a CS if DNA is being requested from the WIHS DNA Repository, specimens will be used by the investigator to create his/her own genetic materials for study, GWAS data will be used, or if any genetics analysis is to be done as part of the concept sheet.

In addition to the review outlined above, concepts that require new forms to be added to the WIHS visit will also require full EC approval and will only receive *provisional approval* until they are discussed during the semiannual WIHS protocol review process. This process consists of the review and discussion of protocol amendments and additions and takes place 3 months prior to the start of the visit window (i.e., July or January). There are only two protocol review discussions per year and so investigators must plan accordingly and submit concept sheets and forms with adequate time for review and revision so that they do not miss the WIHS protocol review deadlines.

No one substudy can take precedence. Once a concept sheet, and the related protocol/forms, are approved by the EC during the semi-annual WIHS protocol review process, an implementation timeline can be developed. Given the length of the standard WIHS interview and the administrative activities required to implement a protocol at each site (e.g., IRB submission, contract approval, staff training) study concepts usually cannot be implemented during the following visit window. In addition, once a study is approved, it will cue up behind other approved concepts for implementation at future visits.

2. **MUTLI-SITE INVESTIGATIONS THAT REQUIRE NO ADDITIONAL DATA COLLECTION**

   WIHS-wide concepts that require no additional data collection (i.e., seek to analyze existing data or specimens) are posted for review and are assigned a Principal Investigator Reviewer (PIR); as well as a Lab Reviewer (LR), if withdrawal of specimens from the central repository is proposed; and/or a Genetics Reviewer (GR), if DNA is being requested from the WIHS DNA Repository or if any genetics analysis is to be done as part of the concept. No review is required from a Project Director (PD).

3. **SINGLE-SITE INVESTIGATIONS**

   Single-site investigations are those that propose to utilize and/or collect data from one site only. All site-specific concept sheets are assigned a PIR from that specific site and then posted for review. The site PI review will ensure that there is no scientific overlap. If additional data is to be collected, the site PD must also approve. Site-specific investigations do not require Lab or Genetics Review. Once the reviews are complete, the project may proceed.

Each concept will have an initial two-week (10-business-day) review period. During this period, all EC members will have the opportunity to post comments about the CS, and the PDR/LR/GR will post their reviews to the WIHS Forum. At the end of this two-week period, the PIR will have two additional days to post the results of the review along with his/her ultimate recommendation for approval or rejection. PIRs should consider comments made by EC members, the PD/LR/GR reviews, the significance of 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 (1) approved as is, (2) approved with comment, (3) approved with major revision, or (4) rejected. If, after review, the PIR thinks additional discussion is necessary for a given CS, then the project can be discussed during the next scheduled EC conference call. This additional review may be scientific (e.g., questions related to: is science relevant to WIHS, should project be high priority, etc.), or operational (e.g., questions regarding implementation, overlap, etc.) in nature. As previously mentioned, 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.

NOTE: *If a concept is submitted as part of a grant application, it will receive administrative review only from the PIR (review for feasibility and overlap), though it will also receive PDR and LR/GR, as appropriate, to determine feasibility and budget appropriateness.*

Investigator(s) who are submitting the concept as part of a grant application may request a Letter of Support (LOS) from the EC after the concept has received provisional approval. Requests for LOS should be sent to WDMAC (jhsph.wdmac@jhu.edu).

If the grant is not funded, and the investigator would like to proceed with the project anyway, full scientific review by the PIR will be necessary before the project may move forward. In this case, the CS should be resubmitted to WDMAC as an amendment with a copy of the study section comments for PIR re-review.

Once a final decision is made, WDMAC, on behalf of the EC Chair, will send a letter of project approval or rejection to the lead investigator within one week of the final decision. During the week following approval WDMAC will also assign the concept README number. This number will be used in all ensuing communication throughout the life of the project. If a study will be using data or specimens collected WIHS-wide, co-authors will be identified from each site immediately after the concept is approved. These co-authors should be listed on any abstracts and manuscripts that are submitted as part of the aims outlined in the concept sheet (see **Section II. Publication Policy** for additional information).

C. CONCEPT SHEET REVISIONS

In cases where a concept requires revisions prior to approval, investigator(s) should make the necessary changes as quickly as possible. Investigator(s) 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. Where possible, the original PIR, PDR, LR and/or GR will be assigned to review the revised CS. Investigators who wish to amend an already-approved CS (either to revise the aims or request additional specimens and/or data) should revise the original CS Submission Form – taking care to highlight any changes.

Revised CS that are approved will either (1) be assigned an initial README number, if it is an initial concept approval; (2) be assigned the same README number as the original project, if the amendment requests additional resources (e.g., data or specimens) solely for completion of the initial project; or (3) 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 or will significantly expand the scope of concept.

D. WIHS DATA AGREEMENTS

Specimens and data provided by the WIHS are intended for the express purpose of performing EC-approved research. These specimens and data must not be provided to other investigators or used for additional projects without the written consent of the WIHS Executive Committee (EC). Failure to follow these guidelines may result in the withdrawal of approval of the study concept.

Unauthorized use of data and/or specimens for work not specifically described in the aims of the concept sheet will be considered a breach of professional ethics and could result in such actions as withdrawal of abstracts or publications, as well as the prohibition of future use of cohort data and specimens.

Additionally, all investigators who are requesting DNA from the WIHS DNA Repository, or are proposing any genetics analysis, are required to submit a signed Genetics Data Use Certification Agreement: *http://statepiaps.jhsph.edu/wihs/index-invest-info.htm*. Investigators may not initiate any research activities until the requisite documents are received by WDMAC. All forms must be submitted to the WIHS Data Management and Analysis Center (WDMAC) electronically (jhsph.wdmac@jhu.edu).

E. EXPIRATION AND DEACTIVATION OF CONCEPT SHEETS

The lead investigator for each approved concept sheet must submit an annual progress report (*http://statepiaps.jhsph.edu/wihs/index-invest-info.htm*) to WDMAC by August 30th each year. A Progress Report will not be due until the next year for Concept Sheets approved less than six months prior to the August 30th deadline (i.e., after March 1st). Annual email reminders will be sent to investigators, but it is the responsibility of the investigator(s) to ensure that the progress report is completed and submitted on-time. If no progress report is received after one email reminder, approval for the Concept Sheet will expire.

If a completed progress report indicates that no activity is occurring on the project or no progress report is received by the due date, the project will be declared inactive.

II. PUBLICATION POLICY

Manuscripts or abstracts resulting from approved concept sheets MUST be submitted and reviewed by the WIHS EC prior to submission for presentation or publication. Final revisions also must be approved by the WIHS EC and co-authors before resubmission. Failure to comply with this policy may lead to such actions as withdrawal of abstracts or publications, as well as the prohibition of future use of cohort data and specimens.

If the approved CS is WIHS-wide, WDMAC will solicit for co-authors from the appropriate WIHS sites as delineated below. Sites are required to post their proposed co-authors to the WIHS Forum within two weeks of solicitation. 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.

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/).

For **multi-site concepts that include pre-2013 data:**

- The offer for co-authors will continue to include the Los Angeles site; Joel Milam is the contact person for assigning a co-author from LA.
- When the CS is posted for review, if an investigator from one of the new Southern sites has expertise and is interested in participating in the concept development, the site PI or co-PI should email WDMAC requesting his/her inclusion in response to the request that goes from WDMAC to the sites for co-authors for the approved CS.
- A CS proposed by a lead investigator from a Southern site that makes use of existing (i.e., pre-2013) data would be handled in the same manner as currently described below (**Section II.A.3.b**), under Authorship for Projects Led by "External" Investigators.

For **multi-site concepts that include post-2013 data:**

- Authorship assignment will follow the existing publication policy that offers co-authorship to **all** sites involved in the collection of data, including WDMAC.

NOTE: *If lead investigators know at the time of concept sheet development that they are considering submission to journals that limit the number of co-authors, then this information and a rationale should be included in the concept sheet proposal so that details of co-authorship can be worked out in advance. In the case of **re-**submission to a journal with limitations on the number of authors, the journal should be approached to allow for inclusion of all co-authors and if this is not successful the issue should be discussed with the co-authors. If no resolution is reached with the co-authors, then the issue will be brought to the EC for an arbitrated decision. In principle, WIHS supports publication in journals that acknowledge the role of large databases and collaborative research.*

A. 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 review (**Section C** 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 an example of the suggested format for 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 I.C**, 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 be 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. MULTI-SITE INVESTIGATIONS

A multi-site investigation is one wherein analyses will utilize data from a subset of the WIHS clinical sites. For these investigations, site representation will be solicited only from the sites contributing data and/or analytic support.

3. CORE INVESTIGATIONS

A core investigation is one using data generated as part of the principal WIHS collaborative agreements (i.e., all 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.

a. Authorship for Projects Led by WIHS Investigator

Core investigations led by a WIHS investigator require that each of the 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 Principal Investigators to request assignment of co-authors as delineated above in **Section II.A**. 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.

NOTE: *If a site's sole contribution to a project will be the provision of data, then the site will be allowed to name only one co-author. Additional co-authors from a site may be added at the discretion of the lead author and would need to be based on individual contribution to the project.*

b. Authorship for Projects Led by "External" Investigator

Core investigations led by an external investigator also require that each of the 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.

4. NESTED INVESTIGATIONS COLLECTING NEW DATA

WIHS funding through the core 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 through core WIHS collaborative agreements (including WIHS Principal Investigators).

In general, the co-authorship guidelines for nested investigations will follow those for single-site, multi-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.

5. **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 will contact the WIHS WG chair with expertise in the area of investigation for help in selecting a WIHS co-author(s) for these projects.

NOTE: *If a project initially is planned as multi-cohort (e.g., WIHS/MACS), but then later changes to WIHS-only, co-authors from all WIHS sites that have contributed data must be added to the project.*

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.

6. 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.

B. 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 begin 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 DVD to all site Data Managers. All data requests that cannot be filled at the local level should be submitted to WDMAC on a ***Data Request Form*** (http://statepiaps.jhsph.edu/wihs/admin/forms-investigator/forms-investigator.htm) via e-mail (jhsph.wdmac@jhu.edu). The form 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.

2. SPECIMEN REQUESTS

All specimen requests should be submitted WDMAC (jhsph.wdmac@jhu.edu). 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 Precision 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 an approved 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

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 currently 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.

C. **MANUSCRIPT REVIEW**

Full EC review is mandatory for all manuscripts using WIHS data, including site-specific manuscripts and manuscripts led by an external investigator. Co-author(s) must participate in the writing and/or review process of manuscripts in a timely manner. Co-authors should be given at least a two-week timeframe to review a manuscript and provide revisions/suggestions. If, after the two-week review period has concluded, the lead investigator has not heard back from a co-author, he/she should adhere to the following process:

- Send a reminder email to the co-author. The co-author should be given three business days to provide revisions/suggestions.
- If the co-author does not respond within three business days, send a second reminder email to the co-author. The co-author should be given three business days to provide revisions/suggestions.

If the lead investigator does not hear back from a co-author after sending two reminder emails, the co-author may be removed from the manuscript. **If a co-author is removed, the lead investigator must notify the co-author's site Principal Investigator.** If the co-author is external to the WIHS, the lead investigator must notify the EC.

It is also the responsibility of the co-author to sign journal copyright forms in a timely manner, once the manuscript is submitted. If a co-author does not sign the copyright form

in a timely manner, the lead investigator can exclude that co-author from the current and subsequent manuscripts related to the approved concept sheet.

Once the manuscript has been approved by all co-authors, the lead investigator should submit it electronically to WDMAC (jhsph.wdmac@jhu.edu) using the ***Manuscript Submittal Form*** (http://statepiaps.jhsph.edu/wihs/admin/forms-investigator/forms-investigator.htm). Manuscripts submitted without full co-author approval or 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 plus two-day deadline will be established for the PIR to review the manuscript.

WDMAC will post the manuscript to the WIHS Forum and notify the PIR, 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 members' comments and complete the ***Manuscript Review Form*** (http://statepiaps.jhsph.edu/wihs/admin/forms-investigator/forms-investigator.htm) by the end of the 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 plus two-day 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 EC. Also, if the resubmitted manuscript is again not approved by the PIR, the author may appeal to the EC. If the author decides to appeal the PIR's decision, discussion of the manuscript will be added to the agenda for the next scheduled EC call.

D. ABSTRACT & PRESENTATION REVIEW

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 jhsph.wdmac@jhu.edu.
- WIHS-wide abstracts require co-authors from each WIHS clinical site, as well as WDMAC. 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 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 abstract submission guidelines apply.

Investigators must email their proposed abstract to WDMAC at jhsph.wdmac@jhu.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.

E. JOURNAL SUBMISSION

The lead investigator must notify WDMAC 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 (jhsph.wdmac@jhu.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.

F. 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).

III. 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 – SUGGESTED WIHS ACKNOWLEDGMENT

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