**WOMEN'S INTERAGENCY HIV STUDY**

**Collaboration Concept Sheet Submission Form & Guidelines**

**STATEMENT OF AGREEMENT**

Top of Form

|  |
| --- |
| I hereby acknowledge and agree that: |
| * All information that I provide in this Concept Sheet is complete and correct as submitted.
 |
| * I have read the Concept Sheet Guidelines (see Appendix to this form) and the WIHS Publication Policy *(*<http://statepi.jhsph.edu/wihs/wordpress/publication-policy/>*)* and agree to follow all the guidelines and processes that are outlined therein.
 |
| * The submitting site PI or, for external investigators, a WIHS liaison, has reviewed the completed Concept Sheet and approved the submission to WDMAC. (*If no liaison exists, email* *jhsph.wdmac@jhu.edu* *to have one assigned.)*
 |
| * If this proposal requests the use of genetics data and receives approval, I will submit the WIHS Genomics Data Use Certification Agreement (<http://statepi.jhsph.edu/wihs/wordpress/investigator-how-tos/>) PRIOR to initiating any research activities.
 |
| * Use of specimens and/or data is restricted to the aims outlined in Section B3 of this Concept Sheet Submission Form.
 |
| * Manuscripts or abstracts resulting from approved Concepts MUST be submitted to and approved by the WIHS EC **prior to** submission to a journal or conference.
 |
| * Under no circumstances will I make the WIHS study subject ID numbers public, whether in documents or presentations, e.g., journal articles, abstracts, oral or poster presentations, or on any website.
 |
| * The lead investigator for each approved Concept Sheet must submit an annual progress report (<https://goo.gl/forms/WTFkF0PvTUiyufHk1>) by August 30th each year. If no progress report is received after one email reminder, approval for the Concept Sheet will expire. 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).
 |

Bottom of Form

My signature (PDF electronic signature) below indicates that I have reviewed, accept, and will adhere to the Guidelines for collaboration, publication, and acknowledgment as outlined in the attached Concept Sheet Guidelines and the WIHS Publication Policy.

Top of Form

**Investigator e-Signature**

Bottom of Form

**SUBMISSION INSTRUCTIONS**

Email completed Collaboration Concept Sheet Submittal Form to *jhsph.wdmac@jhu.edu**.*

**A. GENERAL INFORMATION**

**1. Lead Investigator(s):**

Institution:

Address:

 Telephone Number:

 Email:

**2. Study Title:**

**3. Topic** *(please select up to three from the following topics)***:**

|  |  |
| --- | --- |
| [ ]  Behavior/Psychosocial/Drug Use | [ ]  Cancer/Pathology |
| [ ]  Epidemiology | [ ]  HPV  |
| [ ]  Female Genital Tract/Pathogenesis  | [ ]  Hepatitis/Liver |
| [ ]  Genetics  | [ ]  Metabolic/Vascular |
| [ ]  Gynecology/Pregnancy  | [ ]  Neurocognition  |
| [ ]  Statistics/Methodology  | [ ]  Aging  |

**4. Contact Person** (*if different from lead investigator*)**:**

**5. Submission type**: [ ]  Initial Date of submission:

 [ ]  Revised Date of **initial** submission:

 Date of submission of this revision:

 [ ]  Amendment Date of **initial** submission:

 Date of submission of this amendment:

 Readme# of previously approved concept:

**6. Summary of Changes**: If submission is a revision (to a previously rejected) or an amendment (to a previously approved) existing concept sheet, please summarize all changes. (**NOTE:** In addition, please highlight all changes to previously submitted concept sheet.)

|  |
| --- |
| **WDMAC Use Only - DO NOT REMOVE**  |
| SUB date:      | LLS?:      |
| REV & PDR/LR/GR end:      | DIST date:      |
| PIR:      | PDR:      | PIR end:       |
| LAB:      | GEN:      |  |

**7. Sites involved in the proposed study:** [ ]  All WIHS sites [ ]  All WIHS sites except LA

|  |  |
| --- | --- |
| [ ]  Atlanta  | [ ]  Chicago |
| [ ]  Birmingham/Jackson | [ ]  District of Columbia |
| [ ]  Bronx | [ ]  Los Angeles  |
| [ ]  Brooklyn | [ ]  Miami |
| [ ]  Chapel Hill  | [ ]  San Francisco |

**8. Proposal includes:**

 [ ]  WIHS only

 [ ]  WIHS and MACS

 [ ]  Other cohorts (specify):

**9. WIHS Liaison (if lead investigator is not a WIHS investigator):**

 Name:

 Institution:

 E-mail Address:

WIHS liaison has reviewed the completed Concept Sheet and approved the submission to WDMAC?

 [ ]  Yes [ ]  No

**10. IRB & Human Subjects Issues:**

1. Does this project have IRB approval? [ ]  Yes [ ]  No

If “No”, please provide explanation and timeline for IRB submission:

1. Time period of IRB approval:       to
2. Local IRB reference #:
3. Do you have or will you be obtaining a Certificate of Confidentiality from NIH? [ ]  Yes [ ]  No

**11. Grant Information:**

1. Proposed study is related to an existing grant?

 [ ]  Yes (*please indicate the sponsor and, if NIH-supported, indicate the grant number*)

* + 1. [ ]  NIH Sponsor:      Grant Number:
		2. [ ]  Other sponsor (*please specify*):

[ ]  No

1. Proposed study is related to a pending grant submission?

 [ ]  Yes (*please indicate the sponsor and, if NIH-supported, the solicitation number*)

1. [ ]  NIH Sponsor:      Solicitation Number:
2. [ ]  Other sponsor (*please specify*):
3. Grant submission deadline:

 [ ]  No

1. If you answered “No” to both 11a & 11b, please indicate the source of funding for this proposed study:

**12. Conflicts of Interest Disclosure:**

1. Do any of the investigators have any financial conflicts of interest to disclose?

 [ ]  Yes [ ]  No

If “Yes” please explain:

**13. International Collaborations:**

Regardless of whether or not a subcontract is arranged, will this collaboration involve an institution or company that is not located in the United States?

 [ ]  Yes [ ]  No

***NOTE:*** *If yes, please keep in mind that collaborations with non-US investigators proposing to use specimens and/or data from NIH-funded awards cannot be initiated without prior NIH approval. Should this Concept Sheet receive Executive Committee approval, the lead investigator at each primary awardee institution involved with the collaboration should immediately contact the NIAID Program Official (Ms. Joana Roe,* *jroe@niaid.nih.gov**) in order to receive further details for obtaining such approval.*

**B. STUDY DESIGN** (*Use the following organization to present your study plan. Take whatever space is necessary to respond completely to each section.*)

 **1.** **Lay Language Summary** (*Provide a one paragraph summary of the study and its impact on participants, written for a 10th grade reading level.*)

 **2. Background** (*Provide a brief description of the rationale for the study, including references.*)

 **3.** **Specific Aims and Hypotheses** *(Specimens and data provided by WIHS may only be used to complete the aims described in Section B3. Additional testing or use of data, including transfer to another investigator, outside the scope of the stated aims and not explicitly stated in the concept is not allowed.)*

 **4. Relevance to WIHS** (*Discussion of consistency with WIHS core aims and scope and potential overlap/synergy with ongoing initiatives.)*

 **5. Study Design** (*Summarize the type of study, study procedures, inclusion criteria, and sample size.*)

 **5a.** Does this project involve additional participant burden**?**

 [ ]  Yes *(check all that apply below)* [ ]  No

 [ ]  New specimen collection needed

 [ ]  New questionnaire administered

 [ ]  New procedure (e.g., MRI, biopsy)

 [ ]  New or additional consent needed

 [ ]  Additional visit required

 If “Yes” detail any anticipated additional WIHS participant burden (in terms of amount of time required, additional visit(s), amount and type of specimens to be collected, etc.) and reimbursement to be provided.

 **5b.** Does this project involve additional WIHS site staff burden (e.g., IRB submission, coordination of participant visits, administration of forms, data management, training etc.)?

 [ ]  Yes [ ]  No

If “Yes” detail any anticipated additional WIHS staff burden (in terms of amount of time required, additional visits, specimens to be collected, etc.).

 **6. Laboratory Methods** (*If applicable, summary of testing to be performed and how new studies will generate data, etc.*)

 **7. Test Results**:

 Will test results be returned to participants?

 [ ]  Yes [ ]  No [ ]  NA

 a. If “Yes,” when and how?

 b. If “No,” why not?

 **8. QA/QC Procedures** (*For studies generating new laboratory data: summarize laboratory QA/QC procedures, participation in recognized programs, past publication, etc., relevant to the proposed investigations or testing.*)

 **9. Data Analysis and Sample Size Calculations** (*Where appropriate, indicate which variables are needed from the WIHS database. For WIHS variables, review data collection forms on the WIHS website at* [*http://statepi.jhsph.edu/wihs/wordpress/data-collection-forms/#forms*](http://statepi.jhsph.edu/wihs/wordpress/data-collection-forms/#forms) *or contact WDMAC at* *jhsph.wdmac@jhu.edu**.)*

 a. Will analytic support be requested from WDMAC?

 [ ]  Yes [ ]  No

 b. If “No,” who will perform analysis?

 c. Has analytic team reviewed the Concept Sheet prior to submittal?

 [ ]  Yes [ ]  No

 **10. Manuscript Will Be Completed by** (*Anticipated month and year in which the manuscript will be ready for submission to the EC for review.*)

 Month Year

**C. SAMPLE SPECIFICATIONS** (*Specimens obtained may not be used for any purpose other than the approved project without prior consultation and permission from the Executive Committee.*)

**1. Repository Information:**

1. Will this project require the withdrawal of specimens from the DAIDS Central Repository?

 [ ]  Yes [ ]  No

 Please indicate the date you will require specimens:

1. Will this project require the withdrawal of host DNA from the WIHS DNA biorepository?

 [ ]  Yes [ ]  No

 Please indicate the date you will require specimens:

 **NOTE**: At the time of concept approval, you will need to complete the [WIHS Genomics Data Use Certification Agreement](http://statepi.jhsph.edu/wihs/wordpress/investigator-how-tos/).

 In addition, once the concept is approved please complete the [WIHS DNA Biorepository Sample Request Form](http://statepi.jhsph.edu/wihs/wordpress/investigator-how-tos/#requesting).

**2. Sample Characteristics:** To protect the most valuable and irreplaceable specimens in WIHS, Central Repository requests for specimens from certain groups of WIHS participants (e.g., HIV-seroconverter, ART-naïve HAART initiator, long-term non-progressor, elite non-progressor, incident cancer case, etc.) will trigger additional review by the WIHS Specimen Allocation Committee.

 Please use check boxes to indicate the specifications you will require for your specimen request.

1. Epidemiologic Specifications

|  |  |  |
| --- | --- | --- |
|  | **HIV (+)** | **HIV (-)** |
| **Serostatus** |
|  | [ ]  | [ ]  |
| **Participant Characteristics** |
| Immunologically Defined Disease Progression | *Rapid* | [ ]  | N/A |
|  | *Intermediate* | [ ]  | N/A |
|  | *Slow*  | [ ]  | N/A |
| Clinically Defined Disease Progression | *Rapid*  | [ ]  | N/A |
|  | *Intermediate* | [ ]  | N/A |
|  | *Slow* | [ ]  | N/A |
| Seroconverter | N/A | [ ]  |
| High Risk HIV- | N/A | [ ]  |
| Other (please specify): [ ]  | [ ]  | [ ]  |

 Expected number of Person-Visits to be studied:

Expected number of unique participants to be studied:

1. Will this project require serial specimens with explicitly stated comparisons?

 [ ]  Yes [ ]  No

 If “Yes,” please explain:

1. Sample Type:**\*** [ ]  Serum [ ]  Plasma [ ]  PBMCs (viable) [ ]  PBMC pellet (not viable)

 [ ]  Cervical Vaginal Lavage [ ]  Urine [ ]  Host DNA

 [ ]  Other (specify):

***\* NOTE:*** *Specimens previously thawed for other initiatives may be shipped. If unacceptable, give a reason below for requiring specimens not previously thawed. Leftover material cannot be returned to the National Repository without prior approval from the Repository Program Officer and the WIHS EC.*

1. Sample Quantity: Minimum:       Optimum:

**NOTE: *A data file containing lab results of specimens received, as well as a codebook, must be submitted to the Data Center (WDMAC) prior to the release of visit data to you for analysis. There are absolutely NO EXCEPTIONS to this requirement.***

 **Please read the Guidelines in the following Appendix ➔**

**APPENDIX: Concept Sheet Guidelines**

**A. General Instructions (abbreviated from the** [**WIHS Publication Policy**](http://statepi.jhsph.edu/wihs/wordpress/publication-policy/)**)**

1. All Concept Sheets must be reviewed and approved by the WIHS Executive Committee. The EC will evaluate relevance to WIHS core aims and hypotheses and determine if there is duplication with other WIHS initiatives. Concept sheets that require the development of new forms or collection of additional specimens will need to address logistical considerations related to the proposed activities. **Investigator(s) are required to review the WIHS Publication Policy.**
2. Prior to Concept Sheet submission, Investigator(s) are required to review the proposed research with either their site’s PI (for internal investigators) or a WIHS liaison (for external investigators). If you are an external investigator and do not have a WIHS liaison, contact WDMAC (*jhsph.wdmac@jhu.edu*) for recommendations.
3. Submitted Concept Sheets will be assigned to appropriate WIHS reviewers (PI, Project Director [PD], Laboratory, and/or Genetics) – see WIHS Publication Policy for additional details about the review process. Investigators proposing Concepts that require new forms or additional data/specimens should work closely with the PD Working Group prior to the submission of a Concept Sheet to assess the feasibility of the proposed research and ensure adequate funding is available for the proposed activities. If the Concept Sheet is time sensitive, e.g., related to a grant submission and also requiring new forms or additional data/specimen, then the investigator(s) should contact the PD Working Group chair either directly or via WDMAC (if contact information for the PD Working Group chair is not available to the investigator), **at least 3 months prior to any deadline/submission to ensure that there is adequate time for review.**
4. If the Concept requires additional data/specimen collection, the WIHS EC will review the Concept after it has been reviewed by the assigned PI, PD, Laboratory, and/or Genetics reviewer. At this time the investigator may be asked to participate in a conference call for further clarification.
5. The investigator will be contacted by the EC Chair with information that the Concept was approved, approved with comments, approved for public dataset use, tabled for further clarification, needs to be revised and reviewed again, or was rejected.
6. Approval of Concept Sheets that request use of genetics data is contingent on submission of a Genetics Data Use Certification Agreement. A final EC approval letter indicating approval of the research to commence will be provided once this form is submitted.
7. Approved Concepts requesting specimens must complete a WIHS Repository Request Checklist and/or a WIHS DNA Biorepository Sample Request Form (both available on [*http://statepi.jhsph.edu/wihs/wordpress/investigator-how-tos/*](http://statepi.jhsph.edu/wihs/wordpress/investigator-how-tos/)). The completed form(s) should be sent to WDMAC (*jhsph.wdmac@jhu.edu*) if specimens are to be requested.
8. Please note that ALL abstracts and manuscripts MUST be submitted to the WIHS EC for review and approval before they are submitted to a conference or journal.

**Once a manuscript is accepted by a journal, the lead author will need to send proof of submittal to NIHMS for assignment of a PMCID to** ***jhsph.wdmac@jhu.edu*****.** If you have submitted a manuscript to a journal that initiates the PMCID request, investigators may submit proof that the journal has commenced this process (e.g., manuscript acceptance email with confirmation of NIHMS submission).

1. Upon completion of the analyses specifically defined in the approved WIHS Concept Sheet (i.e., completion is defined as dissemination of study findings in the form of a manuscript submitted to a peer-reviewed scientific journal), the investigator(s) shall, within 60 days, destroy all copies of the limited data set and send a copy of all primary data (i.e., electronic files, hard copy documents) to WDMAC.

**POLICY ON APPROVED USE OF DATA AND SPECIMENS**

* Specimens or 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 non-approved projects without the written consent of the WIHS Executive Committee (EC). Data received from WDMAC may **only** be used for the specific aims of the approved analysis proposed in this concept. Additional research initiatives should be submitted to the EC via completion of a new Collaboration Concept Sheet Submission Form.
* Unauthorized use of data and/or specimens for work not specifically described in the aims of this 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.

**MANUSCRIPTS**

* Manuscripts resulting from collaborative studies must be reviewed by all WIHS investigators who are co-authors. Sufficient time for revision should be allowed before submission to the EC for final approval. EC approval must be received before submittal to a journal. Final revisions also must be available to co-authors for review before resubmission.
* If data analysis for the manuscript has not been carried out at WDMAC, the first author of the manuscript is responsible for sending the computer programs, final data sets and codebooks that directly relate to tables and figures in the manuscript to WDMAC. The programs and data should be labeled table1.dat, table1.sas (if SAS was used), etc., and should be sent *jhsph.wdmac@jhu.edu**.*
* Lead authors should notify WDMAC of any and all manuscripts accepted for publication.
* Lead authors are responsible for complying with the NIH Public Access Policy, that peer-reviewed manuscripts arising from NIH funding and accepted for publication on or after April 7, 2008 are deposited in PubMed Central (PMC). The PMCID or NIHMSID should be sent to *jhsph.wdmac@jhu.edu*along with notification of acceptance for publication or actual publication of a manuscript.

 **ACKNOWLEDGMENT**

All publications and presentations of studies utilizing samples and/or data supplied by the WIHS should acknowledge the contribution of samples and/or data, as well as the WIHS consortia. The suggested language for acknowledgment is below.

*Data in this manuscript were collected by the Women’s Interagency HIV Study (WIHS). The contents of this publication are solely the responsibility of the authors and do not represent the official views of the National Institutes of Health (NIH). WIHS (Principal Investigators): UAB-MS WIHS (Mirjam-Colette Kempf and Deborah Konkle-Parker), U01-AI-103401; Atlanta WIHS (Ighovwerha Ofotokun and Gina Wingood), U01-AI-103408; Bronx WIHS (Kathryn Anastos), U01-AI-035004; Brooklyn WIHS (Howard Minkoff and Deborah Gustafson), U01-AI-031834; Chicago WIHS (Mardge Cohen and Audrey French), U01-AI-034993; Metropolitan Washington WIHS (Seble Kassaye), U01-AI-034994; Miami WIHS (Margaret Fischl and Lisa Metsch), U01-AI-103397; UNC WIHS (Adaora Adimora), U01-AI-103390; Connie Wofsy Women’s HIV Study, Northern California (Ruth Greenblatt, Bradley Aouizerat, and Phyllis Tien), U01-AI-034989; WIHS Data Management and Analysis Center (Stephen Gange and Elizabeth Golub), U01-AI-042590; Southern California WIHS (Joel Milam), U01-HD-032632 (WIHS I – WIHS IV). The WIHS is funded primarily by the National Institute of Allergy and Infectious Diseases (NIAID), with additional co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Cancer Institute (NCI), the National Institute on Drug Abuse (NIDA), and the National Institute on Mental Health (NIMH). Targeted supplemental funding for specific projects is also provided by the National Institute of Dental and Craniofacial Research (NIDCR), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Deafness and other Communication Disorders (NIDCD), and the NIH Office of Research on Women’s Health. WIHS data collection is also supported by UL1-TR000004 (UCSF CTSA), UL1-TR000454 (Atlanta CTSA), and P30-AI-050410 (UNC CFAR).*