WOMEN'S INTERAGENCY HIV STUDY

SECTION 31: WIHS CENTRAL REPOSITORY AND STANDARDIZED SPECIMEN LABELING

I. INCOMING SPECIMENS TO THE REPOSITORY

A. OVERVIEW

Standard protocol instructs sites to send a variety of specimens for each participant seen at each visit to the Central Repository. Beginning midway through visit 11, the WIHS central repository switched from BRinc to Precision Bioservices (formerly known as BBI Biotech and SeraCare Life Sciences). Specimens are collected to fulfill the hypotheses and aims of the WIHS and its sub studies. Before reposited specimens can be requested, investigators must submit a concept sheet for approval by the Executive Committee and applicable Working Groups. After approval, investigators then work with WDMAC to select appropriate person-visits and find specimens.

STANDARDIZATION ACROSS ALL WIHS SITES IS REQUIRED FOR THE FOLLOWING:

- S- CODES
- SPECIMEN ALPHA CODES
- PER TUBE SPECIMEN VOLUMES
- PER TUBE CELL CONCENTRATIONS
- STORAGE TEMPERATURES
- SPECIMENS PER BOX (9X9 GRIDS)
- LABEL INFORMATION
- DATABASE INVENTORY AND BACK-UPS

B. COLLECTION OF WIHS SPECIMENS

See Section 10 for instructions on which specimens are collected at each visit. Processing protocols standardize the expected number of vials with different volume amounts for each specimen type. Local labs are responsible for processing, tracking, storage, and shipment of specimens. Specimen collection is recorded in clinics and labs. Collection compliance and lack of compliance are noted on the forms and entered into the Apollo Data Management System. Many specimens that are collected at the sites do not go to the Central Repository. See Section 10 for instructions on specimens sent for local immediate testing, local save and batch testing, central immediate testing, and central save and batch testing that are not routed through Precision Bioservices.

Most specimens will need to be processed prior to placement in containers for storage. The method of processing will depend on the type of specimen. Since processing of specimens may vary from site to site, refer to the site-specific manual for additional details.

Supplies for storage will be the same as those used by the central repository. These are:

- Tubes: Cryotubes; externally threaded; Fluid volumes of 1.8ml or less should be in polypropylene vials that do not exceed 2 inches in height; Fluid volumes of greater than 1.8ml should be in vials that do not exceed 4.5 inches in height; preferably flat bottomed with screw tops.
- Freezer boxes: 5" x 5" boxes; 2 inches in height.
- Labels: Labels should be placed on each stored tube. Labels cannot exceed the dimensions of (Height/Width): 2.75”/1”, 1.75”/1”, 1”/2.75”, 0.93”/1.75”. Use of inventory sheets to track specimens is optional.

- Polyester Protective Tape (Liquid Nitrogen Safe): Tape should be placed over the preprinted label.

Phone numbers of the suppliers of tubes, tape and boxes are:

- Nunc tubes: Thomas Scientific 800-523-4414
- Sarstedt tubes: Sarstedt, 800-257-5101
- Storage boxes and dividers: Fisher 1-800-766-7000
- Polyester Protective Tape: Fisher 1-800-766-7000

C. RECORDING VOLUME AND SPECIMEN TYPE

1. VOLUME

   The following specimen types may be reposited from the core WIHS visit: serum, plasma, viable cells, cell pellets, CVL, urine, cervical swabs and saliva. Fluid specimens will be aliquotted into cryotubes preferably with flat bottoms and screw caps. Tube height cannot exceed two-inches so that specimens will fit in Precision Bioservices boxes. Volumes for central repository fluid specimens are to be recorded and tracked in milliliters. Fluid volumes should be recorded as 0.5, 1.0, 1.5, 1.8, or 2.0; the actual volume should be +/- 10% of the required volumes. Viable cell and cell pellet concentration should be recorded as 0.5 or 10.0 in the volume field. Record swab and slide volumes as 1.0. Volume unit (e.g., mL) cannot exceed three characters. Volume amounts should be consistent for all sites on every label and in shipping manifests.

   There may be times when there is an insufficient amount of material to meet the aliquot scheme. It is preferred that when aliquoting serum or plasma for shipment to the national repository, vials are filled to the stated volumes. In the event that all vials will not have the full volume, do not distribute the volume evenly among all vials. Fill as many vials as possible to the stated volume. Viable cells should have a concentration of 10 million cells per ml, and if there is not a sufficient amount then the last vial should get no fewer than 6 million per ml. It is more important to have correct volumes in fewer vials than to have less volume in more vials.

2. SPECIMEN CODES

   Three-digit, numeric specimen type codes have been assigned for WIHS central repository specimens. *These numeric codes must be used uniformly by all WIHS sites and included in the files and paper manifests accompanying each shipment to Precision Bioservices.* Alpha codes have also been assigned for use on specimen labels to expedite identifying specimen types in your lab. Sites can opt to use the alpha codes but **must** use the numeric S-code on all specimen labels sent to the central repository.

   Appendix A is a table that highlights the different specimens collected, processed, and aliquotted. Additionally, this table shows the corresponding LDMS coding conventions that should be used by all sites. It is important that use of LDMS codes is standardized across all WIHS labs. Not all specimens are shipped to the central repository (Precision Bioservices); however, specimens sent to the repository must have the numeric S-codes. Specimens must be aliquotted in a standardized manner across all sites and expected tube quantities are also listed in the table.

D. SPECIMEN LABELING AND SHIPPING MANIFESTS

Sites should save specimens in the appropriate local storage facility until the adequate number of boxes can be shipped in standard shipping containers (e.g., 21 or 24 boxes of 81 specimens for Army containers). Central repository specimens should be stored in boxes separate from specimens remaining in the local repository.

1. SPECIMEN LABELING

If the local processing lab does not generate its own labels, the technician will need to verify the following items are on specimens that are sent out:

Participant Study ID#
Date of Specimen Collection
S-code or Collection Tube Type
Visit #

It is essential that barcode formats are the same for all sites, regardless of shipping destination. Symbology format for the barcoded label should be Data Matrix. Visible information on the vial should be in 8-point font. When scanned, the 2-dimensional barcode should read the unique identifier. The following diagram shows the format for visible variables and the location of the barcode:

############ Line 1: [Unique Identifier per vial, 11 characters including a hyphen separating the last two digits] Line 2: [8 character WIHSID] Line 3: [dd]/[mmm]/[yyyy] Line 4: [LDMS primary] [additive] [derivative] Line 5: [Volume] [WIHS 3-digit Numeric Specimen Code]

Acceptable Label Types:

- Brady B-461
- Brady Thermal Transfer Labels (3,000 labels / roll) 1" x 1" writable area. Manufacturer Part # THT-131-427-3
- Shamrock specialty imprinted LBL-M repeat item, 1 ¾" x 1", clear, 1ML Mylar poly with supercolor seal for lamination/perm, Strip only style, Type use wind, White tint to cover 1" white square, Notch in liner and front edge between labels, 1ML clear overlay, 1000 per roll on 3" core

Acceptable Printer (must have a minimum of 300 dpi) and Ribbon Types:

- Zebra Z4M Printer Direct/Thermal Transfer Printer, 203 dpi, 4.5” print width
  - Zeb-5095bk04045-roll, resin ribbon 1.57” x 1476”
- Zebra 110 XiIII Plus
  - Brady Ribbon Part # R4311
- Brady 300 MVP

Supplier Contacts:

- Julie Schoenborn
  Brady Corporation
  P: 800-541-1686 ext 7296
  www.bradylabid.com

- Suzanne Warner
  Shamrock Scientific Specialty Systems, Inc.
  34 Davis Drive
  Bellwood, IL 60104
  P: 1-800-323-0249, 630-842-5213
  F: 1-800-248-1907
  E: skdwerner@aol.com

- CIM Bar Code Technologies (printer ribbon)
  350 Pfingsten Rd Suite 102
  Northbrook, IL 60062
  P: 847-559-9776, ext.14
  F: 847-559-9098

- Accuware, Inc. (Zebra Z4M printer)
  PO Box 423
  Glen Ellyn, IL 60138-0423
  P: 630-858-8409
  F: 630-858-8410

2. SHIPPING MANIFESTS

A paper and an electronic manifest should accompany every shipment. Sites should email the electronic copy for Precision Bioservices manifests to the general e-mail account (daids@precisionformedicine.com) and the current repository manager (Corinne Scully, corinne.scully@precisionformedicine.com). The electronic file should be a .CSV. Sites should communicate directly with all other receiving destinations on manifest format prior to shipment. Columns in the manifest should be in the following order:

1. Global Specimen ID (Per vial unique identifier)
2. Group (This should generally be listed as “WIHS”)
3. PID (WIHSID)
4. VID (Visit in XXX.XX format, a leading zero is not necessary)
5. VID Unit (This should generally be listed as “Vst”)
6. Draw Date (Date of Collection, DD/MMM/YYYY)
7. Draw Time (This is generally left blank.)
8. Prim (LDMS specimen code for primary specimen type)
9. Der (LDMS specimen code for derivative)
10. Add (LDMS specimen code for additive)
11. SCODE (Numeric WIHS S-code in three digits with leading zeroes)
12. Volume
13. Volume unit
14. Custom Local ID
15. Box (Box number in shipment)
16. Row,Col (Row and Column in the Box in the same field separated by a comma)
17. Condition
18. Comment
19. Protocol (This is generally left blank)

3. LABEL QUALITY ASSURANCE PROCEDURES

WIHS specimens need to be clearly labeled to ensure the ability to perform current and future testing on correctly identified specimens. The Laboratory Data Management System (LDMS), created by Frontier Science Foundation (FSTRF), was chosen to be used by all WIHS labs to log, track, and ship specimens starting February 1, 2005. Datamatrix barcodes are available on LDMS version 5.0 and higher labels. The use of the barcodes with appropriate scanners and software will increase the accuracy and productivity in the laboratory and repository. Quality control

checks of the LDMS labels printed for WIHS specimens must be performed to assure the functionality of the labels.

Beginning in January 2005, DAIDS shipments became eligible for rejection and return if a shipment had an unacceptable error rate. Shipments containing greater than 1000 vials may have no more than a 1% discrepancy rate. Shipments that contain fewer than 1000 vials may have no more than 5%, or no greater than 15 vials, with discrepancies. Volume discrepancies will not contribute towards the error rate since both the site-reported and repository-observed volumes are entered into the repository's database. All shipment batches that are rejected will be returned to the site that submitted the specimens to the repository. Sites are responsible for taking appropriate corrective actions, relabeling, and instituting preventive measures to ensure that the same problem does not occur in the future.

a. Each WIHS laboratory should be furnished with appropriate labels, printers, and scanners supported by FSTRF. No less frequently than on each day of use or after each roll of labels is installed or following any necessary corrective action with the printer, the following quality assurance measures should be taken:
    i. Prior to affixing labels to a set of specimen aliquot vials, perform a visual check on the first 5 labels on each study subject. Check to see that all information is printed on the appropriate place on the label and that all information is legible, i.e., information at edges is adequately dark and legible.
    ii. Prior to affixing labels to a set of specimen aliquots vials, scan the first 5 barcode labels on each study subject with an appropriate barcode scanner to assure that they are electronically readable.

b. For each WIHS participant's labels that are printed, the following items must be confirmed before aliquoting specimens:
    i. Confirm that all printed material is correct (i.e., WIHSID, date, and visit number). Positive identification from original tube vial to aliquot tube must be made for each tube.
    ii. Additionally, for each specimen tube type, the primary, additive, derivative, sub-derivative, s-code, volume and volume unit must be confirmed.

c. Prior to shipment, sites should compare the visual and scanned information to the LDMS-exported manifest. Discrepancies should be corrected prior to shipment so as to avoid rejection of specimens by the repository.

E. REQUIREMENTS FOR SHIPMENT

Specimens shipped to Precision Bioservices must be stored in boxes that contain a 9 X 9 grid. The grid will be labeled 1-9 across and 9-1 down to allow easy identification of each location and compatibility with Precision Bioservices's database. Sites should communicate directly with all other receiving destinations on shipping format prior to shipment. Tubes are to be placed in the appropriate box for that specimen type in order from 1-9 across and 9-1 down.

Specimens that the repository will re-direct to a testing facility should be stored in separate boxes. Additionally, specimens that require storage -70º F should be in separate boxes from specimens that have different storage temperature requirements. Snake-pattern filling of the boxes is not necessary. Boxes will be numbered consecutively beginning with 001 at each site for each shipment. Sites are responsible for retaining documentation of specimen allocation and shipment.

Do not send shipments to Precision Bioservices unless they have been scheduled per the procedure established for the WIHS. Sites cannot pre-assign locations for the national repository. See section

II.F. for instructions on how to obtain Precision Bioservices freezer locations using their inventory database, named the BioSpecimen Inventory System-II (BSI-II).

1. PRIOR NOTIFICATION OF SHIPMENTS

When notifying Precision Bioservices of a shipment, sites must first email ChemTel. Current shipping regulations require that a 24-hour Emergency Contact be listed for each shipment containing dangerous goods being transported into, out of, or within the United States. ChemTel is the vendor Precision Bioservices uses for this purpose. Notification should be sent to the 24-hour Emergency Contact prior to the shipment leaving the facility. This phone number must be answered by a person (not by voicemail or computer) 24 hours a day, 365 days a year. The person answering this phone must also possess sufficient details regarding the dangerous goods within the shipment to advise Emergency Response Personnel as to the type of hazard the shipment contains.

ChemTel has specific requirements for the format of the email. The following items must be within the text of the email notification:

i. Shipment Type (i.e., Ambient, Dry Ice, LN2)
ii. Study ID
iii. Study Specific Shipment Number, if applicable
iv. Center submitting the specimens
v. Courier
vi. Courier Tracking Number
vii. Date Shipped
viii. Expected Arrival Date
ix. Address and contact information for Shipper
x. Address and contact information of the intended recipient
xi. Estimated volume
xii. Dangerous goods classification (i.e., Diagnostic Specimens, Dry Ice)
xiii. Estimated Volume or Quantity of each Dangerous Good
xiv. Estimated number of Specimens
xv. An electronic copy of the shipping manifest in a pre-approved format

Additionally, the Subject Line of the email notification must contain the air waybill or courier tracking number without hyphens, spaces or other characters.

Please note that notification by facsimile is allowed if the Shipper does not have access to email, but should not be used as there is an additional charge incurred for this service. In addition, facsimile notification will delay the ability of ChemTel personnel to respond to questions regarding a shipment during a crisis.

When you send notification to ChemTel you should copy the email to Precision Bioservices, thus meeting the requirement of prior notification with the consignee detailed in IATA DGR Section 1.3.3.1.

Email TO address:	BBIBIOTECH@chemtelinc.com
Email CC address:	daids@precisionformedicine.com
Email Subject:	airway bill or courier tracking number
Fax Number:	(813) 248-0582
Phone Number(s):	(800) 255-3924 (primary) or (813) 248-0585 (secondary)

F. RECEIPT AND ACCESSIONING OF SPECIMENS

Shipments are received via courier at Precision Bioservices and specimens are immediately transferred to a temporary freezer. Precision Bioservices staff record the date, study, site, and date of receipt on each box in the shipment. All documentation concerning the shipment is filed in a folder that is created after storage in the temporary freezer. A Confirmation of Shipment Receipt form is completed and emailed to the site. Contact Precision Bioservices directly to query the status of specimens in temporary freezers.

During the review and data entry of the shipment, the repository performs a 100% quality control check of all identifiers on vial labels compared to the electronic manifest received from the site. A supervisor is informed of any discrepancies and a second employee independently verifies those discrepancies. Upon completion of the review of the shipment, Precision Bioservices emails the Discrepancy Form to the shipping contact even if there are no discrepancies identified. The site should respond with corrective actions within 5 business days. Corrective actions as directed by the site are implemented and new labels are printed if necessary.

Corrective actions may require modifying the data received in the electronic manifest from the site. These changes are made and then verified to have been keyed correctly by a member of the laboratory staff. Verification is completed before the data is committed to the inventory database.

Once the modifications have been verified, the data entry batch is then committed to the BSI-II and all documentation is filed in the shipment folder. The shipment is then considered complete and specimens are available for review or withdrawal in the BSI-II.

G. WIHS TRACKING OF SHIPMENTS TO THE CENTRAL REPOSITORY

In order to ensure timely commitment of WIHS specimens to the central repository, the WIHS needed to centrally track shipments to the repository using the Apollo web-based data management system. Beginning with visit 30, the repository commitment rate was consistently stable so that sites no longer needed to complete the CRST form. Sites should still maintain thorough documentation of all WIHS shipments to the central repository so that they can accurately respond to the central repository's questions about shipments.

H. REPOSITORY FILES

Every six months, following the central edits and creation of the visit data freeze, the WDMAC Data Manager requests a dump of the BSI-II database containing the entire available WIHS specimen inventory. This data dump includes all WIHS specimens residing in the repository, but does not include information on specimens for specific substudies, such as the Metabolic Substudy.

Repository files are edited by merging them with the WDMAC summary files DATEBASE and WIHSIDS. This process checks for correct WIHSID numbers, transfer ids, visit numbers, and visit dates. For example, if the repository's visit date for a given visit number does not match the WIHS visit date, then the alternate date is also kept in the file. This occurs in less than 5% of total records. Output frequencies help verify that recently accessioned records are correct and inconsistencies are investigated by WDMAC and Precision Bioservices.

Data files are split by specimen type according to S-code and/or material modifiers. The files are checked by WDMAC programmers during sample selection for outgoing requests. WDMAC produces periodic reports on the status of specimens in the repository. Investigators who need specimens from more recent visits should monitor the repository reports to determine when visit specimens are available and then submit new requests for completion. Finally, the BSI-II has very useful generic and individualized reports.

II. OUTGOING SPECIMENS FROM THE REPOSITORY

A. REQUESTS TO WDMAC

Investigators must submit initial inquiries to the WDMAC Project Coordinator, Christine Alden (calden@jhsph.edu), 410-223-1658. A WDMAC Statistical Programmer (WSP) will be assigned to work with investigators to select specimens. Investigators requiring specimens that are not yet committed to the central repository can contact local repositories to arrange for shipment of local specimens; local repositories are outside the purview of WDMAC oversight.

Many factors contribute to the study group selection, such as the focus of the laboratory assay, serostatus requirements, HAART status, rate of disease progression, and whether progression should be defined clinically or immunologically, to name just a few. Investigators should consider all relevant selection criteria when sending sample specifications to WDMAC. The request will go through at least 2 rounds of quality assurance before submission to the repository.

1. Investigators must complete and sign the WIHS Repository Request checklist (http://statepiaps.jhsph.edu/wihs/Invest-info/ReposCheckList.doc), which includes:

    - The Readme number for the project
    - Investigator contact and email information
    - Specimen Type
    - Total expected number of specimens
    - Minimum acceptable volume
    - Lab that specimens should be shipped to, including name, address and at least one phone number
    - Freeze/thaw info – preferred method of shipping (dry ice, liquid nitrogen) and whether or not pristine specimens are required, if Precision Bioservices should thaw and aliquot
    - Special instructions: Should the repository pack vials for shipment in any particular order? Does the project require blinded/relabeled specimens? What variables will the testing facility need on the manifest from the repository? What is an acceptable file format for the manifest so that the testing facility can incorporate the file into their tracking system?
    - Signed assurance that the project has local IRB approval

    Investigators requesting DNA should use the DNA Biorepository Request checklist (http://statepiaps.jhsph.edu/wihs/Invest-info/DNA_request_form.doc).

2. Investigators must work with the WSP to determine the most appropriate format in which tested data will be returned to WDMAC.

3. Fax or email the completed checklist to the WDMAC Project Director, Christine Alden (fax: 410-223-1666, calden@jhsph.edu).

4. Additional concerns, changes to the request, etc., will be handled via phone or email between the programmer, specimen requestor, and investigator.

B. SUBMITTING FINAL SPECIMEN REQUESTS TO THE WDMAC REPOSITORY COORDINATOR (WRC)

1. A WDMAC Statistical Programmer (WSP) prepares the request for submission to the WDMAC Repository Coordinator (WRC). The requested samples should be in Excel attached to an email with shipment and other information. Repository requests that do not match the following format will be returned, unprocessed.

a. File format:
   - The request is submitted in Excel.
   - The requested number of samples cannot be more than ~250 per Excel spreadsheet. If more than ~250 specimens are being requested, the specimens should be listed in different files or on different spreadsheets.
   - All samples in a request are for one EC approved project (one Readme #).
   - Participants that have a history of transferring between sites should be requested using the WIHSID at the time of collection and not the most current WIHSID.
   - The first row should indicate the readme#, lead investigator for this project, and S-code or Material and Material Type (See Standardized WIHS Specimen Codes, Appendix A).
   - The columns in the Excel file should include at least: WIHSID and Visit #. Draw Date is optional.
   - Visit dates should be in a three-digit format with two or three leading zeroes. (In Excel, select the visit date column, click Ctrl+1 or select Format>Cells, click on the "Number" tab, click "Custom", select the "0", in the "Type" field enter two zeroes, check the Sample box above the Type field.)
   - Fields cannot have extraneous spaces or characters. If a WIHSID and Visit are [10234567] [009] then the repository database reads the space as a character. It will be unable to find either WIHSID or visit and report that there are no specimens for that WIHSID or visit.
   - If the request is unusually large or complex or the receiving lab has specific requirements, consult with the WRC before determining the structure of the request file.

b. Shipping information:
   - All specimens in a request are shipped to one location.
   - Shipment information contains the Laboratory contact person, lab phone, complete address, preferred time of delivery, phone number that will be answered 24 hours a day during the time of shipment, and any other special information regarding the lab's needs in accepting shipments and manifests.
   - Information on preferred method of shipment: preferred shipping container, warmest/maximum/upper bound acceptable temperature for shipping, preferred freezing medium, and preferred transporter (e.g. LN2, Army, Air/Sea).

Sometimes testing necessitates that specimens be shipped in a random order. It is preferable that the request(s) sent to WDMAC be as complete as possible. Investigators and local programmers can easily perform this task in SAS.

3. The WRC will work with all programmers and the lead investigator if problems arise with selecting samples. Alternate specimens may need to be selected.

4. Before submitting, the WRC will verify every record in the request against the initial request and any changes.

5. After the final request is submitted, the WRC will email the requisition number(s) and a file containing the shipping instructions and specimens requested to all programmers and the lead investigator. This file will include special instructions to the repository, shipping task information, BSIID, WIHSID, Visit, Draw Date, Material, Material Type, other task information (mixed order, blinding, relabel, etc.). Shipments are tracked during delivery using this requisition number and the courier's tracking system. Precision Bioservices has a unique identifier for each shipment in the format RYYYY:CCCCCC-X0. R stands for requisition, then the year in four digits, a colon, and finally the chronological assignment of requests submitted to the database in that year. "X0" are the task designations e.g. ship, sort, label. The task will always end in a zero.

The "X" will be a number between 1 and 9 as assigned by the BSI-II. Refer to the specific requisition for task number assignment.

6. Precision Bioservices ship manifest: Precision Bioservices can add many different fields to the ship manifest to assist investigators and labs. The standard manifest includes BSI ID, Material Type, and Volume. Other fields that can be added include, location order in shipment (Box, Rox, Column), S-code, WIHSID, Visit, and Requisition number. Investigators should indicate on the WIHS Repository Checklist their desired manifest fields. Investigators must also indicate to whom the shipment notification and manifest should be mailed as well as the file format of the manifest.

7. Problems may also arise when Precision Bioservices withdraws specimens from the freezers. Investigators again may need to select different samples.

C. LOCALLY PROGRAMMED SPECIMEN REQUESTS AND QC PERFORMED BY WDMAC

In general, Investigators should first contact a WDMAC coordinator regarding repository withdrawals. The following protocol is designed to illustrate the process for repository requests that are locally programmed and then verified by WDMAC.

1. The proposed WIHSID/visit samples, sample type, selection criteria from the EC-approved concept sheet, and project Readme number are emailed to the WDMAC Statistical Programmer (WSP). The WSP may stipulate the exact file format of the submission.

    - The selection criteria can be sent in the body of the email or in an attached Word file. In general, local programmers should send a SAS dataset or ASCII file of the specimens selected. This data should include the following information: WIHSID, Visit, and Draw Date. If there are any questions about variables in and format of the dataset, contact the WSP.

2. The WSP will review the files and selection criteria. He/She will QC all aspects of the request including duplication of requested samples within the request compared to previous requests. Additionally, the WSP will make sure the samples selected are consistent with stated selection criteria.

3. Regarding any issues/problems/questions about the samples, the WSP will communicate directly with the lead investigator and any external programmer(s) responsible for generating the list of samples requested. The two parties will resolve any inconsistencies between datasets.

4. Once QC/verification is complete, the WSP will email the final files back to the investigator and local programmer(s).

5. The WSP will complete relevant parts of the Specimen Checklist request form. If a request is for different projects (thus, different Readme #s) then one form is used per project. The local site returns the completed Specimen Checklist request via fax with the investigator's signature. The signature assures that the samples chosen are indeed the correct samples needed for the project. The WSP signs for WDMAC, keeps one copy, and gives the original to the WDMAC repository coordinator (WRC) for the next phases. The WRC will file a copy with the requisition folder and, finally, put the original in the project folder.

Step five ends duties of a WSP. Refer to section II.B. for instructions on how to submit the final request to the WRC.

D. RESTRICTIONS ON SAMPLES

The B-cell immortalization program was ended in July 2004. 60% of WIHS participants have established B-cell lines (73% of the 94/95 cohort and 29% of the 01/02 cohort); however, 20% of WIHS participants did not consent to the creation of a cell line. WDMAC therefore maintains records

on what specimens are not eligible for B-cell immortalization. Fisher (formerly known as McKesson) BioServices maintains specimens created via this program. The program's protocol stipulated that participants would have four vials of viable B-cells and six vials of cell pellets. Only cell pellets can be distributed to investigators. Requests for immortalized samples should follow the process described in part II.A-B.

When an investigator unknowingly requests the last vial, WDMAC will inform the investigator and/or programmer, asking him or her to select alternate visits or WIHSIDs from which another vial may be taken. If this is not possible, the investigator should contact local repositories for the needed specimens. If no alternates are available, then the investigator may request additional review by the WIHS EC to justify the scientific use of those specimens. Only the WIHS EC can approve the release of the last vial of a specimen type, WIHSID, visit unique combination.

All genetic association studies must confirm a participant's genetic consent status in the summary file WIHSIDs prior to requesting specimens and again during analyses.

E. REQUISITION DOCUMENTATION

WDMAC archives all work completed during the sample selection and requisition phases. Sample selection criteria, programs, and data sets are documented by date with local file locations and comments by the staff member performing the work in Readme files. Additionally, the request and withdrawal phases are documented in a folder filed by year and requisition number. All relevant emails, documents, the final list of requested specimens, and the withdrawal process are saved electronically and in hard copy format. Finally, all requests are logged in an ACCESS database by requisition number with information including WDMAC staff persons, Investigator, Readme number, and specimen type.

F. REPOSITORY WITHDRAWAL

Precision Bioservices staff monitor the Requisition Manager of the BSI-II multiple times during each business day. A new withdrawal request will appear in a work list upon submission by the requestor (WDMAC). Precision Bioservices Data Entry staff will print a pull list and a copy of the requisition instructions. These documents are filed in a shipment folder to be reviewed by a Repository Manager.

The Manager will initially review all requisitions submitted by WDMAC the day they are submitted or the next business day. They confirm that EC approval is documented within the instructions from WDMAC and that the instructions are clearly understood. The Manager will contact WDMAC if additional information is needed. Once the approval to proceed is given from the Manager, a Research Associate will begin pulling the vials by freezer location and create a report for any discrepancies found between the vial and the BSI-II. The Associate will also investigate specimens from the same subject/visit date/material type combination to ascertain the extent of the discrepancy identified. Vials that were not accessioned by Precision Bioservices have a higher error rate, so investigators should allow for additional time during the withdrawal process of older specimens.

A Precision Bioservices Supervisor or Manager reviews the shipment and works with WDMAC to resolve any problems or vial discrepancies. Discrepancies are reported to WDMAC in a standardized file. Many discrepancies have standard resolutions; however investigators may be contacted by WDMAC and asked for their decision regarding widespread or vial-specific issues. Precision Bioservices staff will modify the request based on the response from WDMAC and proceed with special instructions (thaw and aliquot, re-label, etc.). Vials that are to be aliquotted by the repository are triple-checked by a supervisor or manager prior to thawing. Aliquots remaining at the repository and the vial designated for shipping are also checked by a supervisor or manager.

Shipping documentation and labeling are double-checked by a second employee trained to ship dangerous goods. A Supervisor or Manager also contacts the recipient identified in the request instructions from WDMAC and confirms the receiving availability of the facility and the shipping

address/phone number. The repository will track shipments through the courier used for shipment and will also obtain verbal or written confirmation of receipt from the receiving facility. The shipping manifest and its format are distributed according to the information supplied by the investigator on the WIHS Repository Checklist.

G. TRANSFER OF RESULTS

1. GENERAL GUIDELINES

   The WIHS Investigators are providing the specimens with the understanding that the WIHS is entering into a full collaboration with the individual study investigator(s) and that all data generated from the WIHS specimens will be provided to the WIHS EC (or WDMAC) in a timely fashion as outlined below. Moreover, the data generated from WIHS specimens will remain the property of the WIHS EC, but the study investigator(s) will have exclusive first rights to the publication of these data as outlined below.

   All data generated from the WIHS specimens must be submitted to WDMAC at the earliest of the following:

   - 1 month following the acceptance of the first paper to be written using the WIHS data.
   - 1 year following the receipt of the WIHS specimens by the study investigator.

   The deadlines specified above are open to negotiation with the WIHS EC. They may be altered only by the WIHS EC with alternate deadlines being specified in a letter drafted by the WIHS EC and addressed to the study investigator.

   To ensure that progress is being made on the testing of WIHS specimens, quarterly updates detailing the status of the testing of the specimens and the preparation of the manuscript must be submitted to the WIHS EC beginning three months after the receipt of the specimens by the study investigator. If the specimens have not been tested within one year of receipt, then the specimens must be returned to the WIHS.

2. REQUIREMENTS OF RESULT DATASET

   The results dataset should be sent via email to the WDMAC Data Manager (gspringe@jhsph.edu) with the WIHS readme number, a brief synopsis of the project, and type of testing performed. Investigators are also responsible for sending a codebook that includes valid result ranges and full test names. If the results are published at the time of dataset transmission, the investigator should also send a complete citation.

   The dataset can be in Excel or ASCII format. At a minimum, the dataset should include the following variables for each record: WIHSID, visit, specimen collection date, specimen testing date, test(s), and result(s).

3. WDMAC ARCHIVE OF RESULTS

   As long as progress is being made toward the publication of the WIHS specimen results, all test results and other related data sent to WDMAC will be kept confidential. It will not be made available for other studies. However, once the sentinel paper has been published, or at the time the WIHS EC determines that a given project is not progressing, then all data generated for that project will be incorporated into the WIHS analysis database and may be made available to all WIHS investigators.

   The data file(s) and codebook(s) will be securely archived as ASCII files under the file name format of readme.testtype (or equivalent).dat, e.g., w01025.fasting.dat.

Appendix A. Standardized WIHS Specimen Codes, Volumes, and LDMS Codes

WIHS				LDMS☼					
SPECIMEN TYPE	ALPHA CODE	S- CODE	EXPECTED TUBE QUANTITIES	Primary	Additive	Derivative	Sub/ Der	Primary Time Unit	Volume§
Serum (red-top or SST)	S	1	500, 1000, 1800	BLD	NON	SER	-	-	0.5∞, 1, 1.8
				BLD	SST	SER	-	-	0.5∞, 1, 1.8
Serum (tiger-top or gold SST, non-fasting)	NTS	3	500, 1000, 1800	BLD	SST	SER	-	-	0.5∞, 1, 1.8
Plasma (CPT)	TP	4	500∞, 1000, 1800	BLD	CPS	PL2	-	-	0.5∞, 1, 1.8
Viable Cells (CPT)	TC	6	1x10E7*, 6x10E6 ♦, 5x10E5 ♦	BLD	CPS	CEL	DMS	-	10.0
Whole blood (lavender, non-fasting)	NWB	8	500	BLD	EDT	BLD	-	-	0.5
Plasma (lavender, fasting)	FEP	9	500	BLD	EDT	PL1/PL2	-	Fasting	0.5∞, 1
				BLD	PPT	PL1/PL2	-	Fasting	0.5∞, 1
Dry Cell Pellets (CPT)	TCP	10	5x10E5*	BLD	CPS	PEL	-	-	0.5
Urine Supernatant	U	12	1000‡, 1500	URN	NON	FLD	-	-	1, 1.8
Chlamydia LCR swab	CLCR	21	1†	CER	NON	SWB	-	-	1.0
Urine, clean void	ULCR	22	1000, 5000	URN	NON	URN	-	-	1.0, 5.0
Oral Fungal Culture	OF	23	1†	ORL	NON	SWB	FUN	-	1.0
Vaginal Fungal Culture	VF	24	1†	VAG	NON	SWB	FUN	-	1.0
Whole CVL fluid	CVL	25	1000, 1500	CVL	NON	CVL	-	-	1, 1.5
CVL supernatant	CVS	26	500, 1000	CVL	NON	FLD	-	-	0.5, 1.0
CVL pellet	CVP	27	250*	CVL	NON	PEN	NSL	-	0.2
Stimulated Saliva	SS	28	1000	SAL	NON	SAL	-	-	1.0
Oral Fungal Culture (for Oral protocol)	OD	30	1†	ORL	NON	SWB	FUN	-	1.0
Plasma (HHV-8; SF only)	HTP	31	500, 1000	BLD	ACD	PL2	-	-	0.5, 1
Serum (HHV-8; SF only)	HS	32	500, 1000	BLD	NON	SER	-	-	0.5, 1
Stimulated Saliva (HHV-8)	HSS	33	1000	SAL	NON	SAL	-	-	1.0
Anal specimens (HHV-8)	HA	34	1†	REC	NON	SWB	-	-	1.0
ACD tube viable cells (HHV-8; SF only)	HTC	35	600*	BLD	ACD	CEL	DMS	-	6.0
ACD tube cell pellets (HHV-8; SF only)	HTCP	36	50*	BLD	ACD	PEL	-	-	1.0
Saliva cells (HHV-8)	SSC	37	50*	SAL	NON	CLN	DMS	-	1.0
Saliva Supernatant (HHV-8)	SSS	38	500	SAL	NON	FLD	-	-	0.5
Cervical Swab for HIV RNA quantitation	CS	39	1†	CER	NON	SWB	GIT	-	1.0 ±

Appendix A. Standardized WIHS Specimen Codes, Volumes, and LDMS Codes

WIHS				LDMS☼					
SPECIMEN TYPE	ALPHA CODE	S- CODE	EXPECTED TUBE QUANTITIES	Primary	Additive	Derivative	Sub/ Der	Primary Time Unit	Volume§
Whole blood (lavender, fasting)	FWB	41	500	BLD	EDT	BLD	-	Fasting	0.5
Serum (tiger-top or gold SST, fasting)	FTS	42	500, 1000, 1800	BLD	SST	SER	-	Fasting	0.5∞, 1, 1.8
Plasma (gray-top, fasting)	FGP	43	500	BLD	SPO	PL1/PL2	-	Fasting	0.5∞, 1
VRS Plasma (CPT)	VTP	44	500, 1000	BLD	CPS	PL2	-	-	0.5, 1.0
VRS Plasma (EDTA): 0 minutes	V00	45	500, 1000	BLD	EDT	PL1	-	-	0.5, 1.0
VRS Plasma (EDTA): 30 min.	V30	46	500, 1000	BLD	EDT	PL1	-	-	0.5, 1.0
VRS Plasma (EDTA): 60 min.	V60	47	500, 1000	BLD	EDT	PL1	-	-	0.5, 1.0
VRS Plasma (EDTA): 120 min.	V120	48	500, 1000	BLD	EDT	PL1	-	-	0.5, 1.0
VRS Viable Cells (CPT)	VTC	49	600*	BLD	CPS	CEL	DMS	-	0.6
Metabolic Substudy: 00 min plasma	MP0	50	1000	BLD	SPO	PL1	-	-	1.0
Metabolic Substudy: 30 min plasma	MP3	51	1000	BLD	SPO	PL1	-	-	1.0
Metabolic Substudy: 60 min plasma	MP6	52	1000	BLD	SPO	PL1	-	-	1.0
Metabolic Substudy: 90 min plasma	MP9	53	1000	BLD	SPO	PL1	-	-	1.0
Metabolic Substudy: plasma: 120 min	MP12	54	1000	BLD	SPO	PL1	-	-	1.0
Metabolic Substudy serum: 00 min	MS0	55	2000	BLD	SST	SER	-	-	2.0
Metabolic Substudy serum: 30 min	MS3	56	2000	BLD	SST	SER	-	-	2.0
Metabolic Substudy serum: 60 min	MS6	57	2000	BLD	SST	SER	-	-	2.0
Metabolic Substudy serum: 90 min	MS9	58	2000	BLD	SST	SER	-	-	2.0
Metabolic Substudy serum: 120 min	MS12	59	2000	BLD	SST	SER	-	-	2.0
Metabolic Substudy whole blood	MWB	60	2500	BLD	EDT	BLD	-	-	2.5
HTLV 1 & 2 re-directs	HTLV	61	500	-	-	-	-	-	-
HSV re-directs	HSV	62	500	-	-	-	-	-	-
Swab (from FGP)	SPO	63	1000	BLD	SPO	SWB	-	Fasting	1.0
Saliva Rinse (pellet)	LAP	64	500,000	SAL	NON	PEN	-	-	6.0
Saliva Rinse (whole)	LAR	65	1000	SAL	NON	SAL	-	-	1.0
Saliva Rinse (supernatant)	LAS	66	1000	SAL	NON	SAL	-	-	1.0
Saliva	SLA	67	1000	SAL	NON	SAL	-	-	1.0
Saliva, Stimulated (pellet)	SLP	68	500,000	SAL	NON	PEN	-	-	6.0
Saliva, Stimulated (supernatant)	SLS	69	1000	SAL	NON	FLD	-	-	1.0
Saliva, Unstimulated (whole)	ULA	70	1000	SAL	NON	SAL	-	-	1.0
Saliva, Unstimulated (pellet)	ULP	71	500,000	SAL	NON	PEN	-	-	6.0
Saliva, Unstimulated (supernatant)	ULS	72	1000	SAL	NON	FLD	-	-	1.0

Appendix A. Standardized WIHS Specimen Codes, Volumes, and LDMS Codes

WIHS				LDMS☼					
SPECIMEN TYPE	ALPHA CODE	S- CODE	EXPECTED TUBE QUANTITIES	Primary	Additive	Derivative	Sub/ Der	Primary Time Unit	Volume§
Smear, Slide	BV	73	1	VGL	NON	SLD	-	-	1.0
Tissue, Slide	DFA	74	1	TIS	NON	SLD	-	-	1.0
Vaginal Tissue	VGL	75	1	VGL	NON	TIS	-	-	1.0
PAP Smear	PAP	76	1	CER	NON	SLD	-	-	1.0
Cervical Tissue (ACSR)	CVB	77	1	CER	NON	TIS	-	-	1.0
Breast Tissue (ACSR)	BRL	78	1	BRS	NON	BRS	-	-	1.0
Tissue (perirectal)	REC	79	1	REC	NON	TIS	-	-	1.0
Hair	HAR	80	Clipping	HAR	NON	HAR	-	-	1.0
Urine (pellet)	UPE	81	Varied	URN	NON	PEN	-	-	1.0
Intensive PK study: 00 minute plasma	P0M	82	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 30 minute plasma	P30	83	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 60 minute plasma	P60	84	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 2 hour plasma	P2H	85	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 2.5 hour plasma	P25H	86	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 3 hour plasma	P3H	87	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 4 hour plasma	P4H	88	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 5 hour plasma	P5H	89	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 6 hour plasma	P6H	90	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 8 hour plasma	P8H	91	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 12 hour plasma	P12	92	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 15 hour plasma	P15	93	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 18 hour plasma	P18	94	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 21 hour plasma	P21	95	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Intensive PK study: 24 hour plasma	P24	96	500, 1000, 1200	BLD	EDT	PL1	-	-	0.5, 1.0, 1.2
Left Ventricular Function study: Plasma (lavender)	LVFP	97	500, 1000	BLD	EDT	PL1	-	-	0.5, 1.0
Herpes Swab	HS	98	1	GLU	NON	SWB	VTM	-	1.0
Anal Cytology	AC	99	1	REC	UNK	CIO	-	-	1.0
Urine Culture	UC	100	1	URN	NON	URN	-	-	1.0
ACSR ACD Plasma	07-Y	101	1000	BLD	ACD	PL1	-	-	1.0
ACSR ACD PBMC	08-Y	102	1000	BLD	ACD	CEL	DMS	-	10.0

Appendix A. Standardized WIHS Specimen Codes, Volumes, and LDMS Codes

WIHS				LDMS☼					
SPECIMEN TYPE	ALPHA CODE	S- CODE	EXPECTED TUBE QUANTITIES	Primary	Additive	Derivative	Sub/ Der	Primary Time Unit	Volume§
ACSR Cervical Control Tissue	CERC	103	1	CER	NON	TIS	TFM	-	1.0
ACSR Cervical Lesion Tissue	CERL	104	1	CER	NON	TIS	TFM	-	1.0
ACSR Vaginal Control Tissue	VAGC	105	1	VGL	NON	TIS	TFM	-	1.0
ACSR Vaginal Lesion Tissue	VAGL	106	1	VGL	NON	TIS	TFM	-	1.0
ACSR Vulva Control Tissue	VULC	107	1	VUL	NON	TIS	TFM	-	1.0
ACSR Vulva Lesion Tissue	VULL	108	1	VUL	NON	TIS	TFM	-	1.0
Oral Rinse (Scope or Saline)	SCR	109	50,000	SAL	OTH	SAL	-	-	50.0
Plasma (EDTA, HIV RNA)	EPH	110	1000	BLD	EDT	PL2	-	-	1.1
				BLD	PPT	PL1	-	-	1.1
Urine Pellet	UPN	111	1000	URN	NON	PEN	PBS	-	1.0 †
HPV DNA swab supernatant	HDS	112	600 - 1000	CER	NON	SWB	DTM	-	0.6-1.0
2011/12 recruits: HCV+ testing	IVHC	113	1000	BLD	NON	SER	-	-	1.0
				BLD	SST	SER	-	-	1.0
2011/12 recruits: Sex steroids	IVSS	114	1000	BLD	NON	SER	-	-	1.0
				BLD	SST	SER	-	-	1.0
2011/12 recruits: hsCRP	IVHS	115	500	BLD	NON	SER	-	-	0.5
				BLD	SST	SER	-	-	0.5
2011/12 recruits: Renal testing	IVRT	116	1000	URN	NON	URN	-	-	1.0
MSK sub study: serum	MSKS	117	1200	BLD	NON	SER	-	-	1.2
				BLD	SST	SER	-	-	1.2
MSK sub study: viable cells	MSKC	118	1x10E7*	BLD	CPS	CEL	DMS	-	10.0
HPV sub study: sodium heparin tube Δ	HPH	119	10,000	BLD	HEP	BLD	-	-	10.0

* Reflects cell concentration in each aliquot and is not a liquid measurement.

† Reflects quantity of vials, not volume.

‡ Collected at visits 1-7, at odd visits 31-35, and at even visits 36+

☼ The "Other Specimen ID" field should be entered with a three digit WIHS S-code, add one or two leading zeroes as necessary.

§ Volume cannot exceed three characters. One character is reserved for the decimal point.

± Cervical Swab for HIV RNA quantitation should have a volume unit of "N/A" in the LDMS. Swab collected at visits 12-28.

♦ The concentration of viable cells was increased from 6x10E6 to 1x10E7 at visit 22. Viable cells with a concentration of 5x10E5 were discontinued at visit 27.

∞ Starting with visit 27, CPT Plasma was placed only in 1ml aliquots. Prior visit protocols have specified 0.5 ml. Starting with visit 29, all core serum and plasma were placed only in 1ml aliquots. Starting with visit 36, one vial each of core plasma and serum was filled to capacity (1.8 ml).

Δ Sodium heparin tube of whole blood for HPV sub study to be shipped overnight without processing locally at ambient temperatures.

Appendix B. WIHS Center Codes in the BSI-II

BBI Code	Site Name	Location
WIH0101	QUEST BRONX LEB	Quest(Bronx Lebanon Hosp. Ctr.)
WIH0102	QUEST BETH ISRAEL	Quest(Beth Isreal Med. Ctr.)
WIH0103	QUEST MT SINAI	Quest(Mt. Sinai Med. Ctr.)
WIH0121	QUEST BRONX LEB	Quest (Bronx Lebanon Hosp. Ctr.)
WIH0122	QUEST BETH ISRAEL	Quest(Beth Isreal Med. Ctr.)
WIH0123	QUEST MT SINAI	Quest: Mt Sinai Med Ctr.
WIH0199	QUEST CORNING	Quest(Corning Clinical Lab)
WIH0201	BROOKLYN SUNY	Brooklyn Consortium(SUNY Brooklyn)
WIH0202	BROOKLYN KINGS CO	Brooklyn Consort.(Kings County Med Ctr)
WIH0221	BROOKLYN SUNY	Brooklyn Consortium (Suny Brooklyn)
WIH0222	BROOKLYN KINGS CO	Brooklyn Consort.(Kings County Med Ctr)
WIH0301	QUEST GEORGETOWN U	Quest(Georgetown U. Med. Ctr.)
WIH0302	QUEST HOWARD U	Quest(Howard U. Med. Ctr.)
WIH0303	QUEST INVOVA VA	Quest:Inova Health Sys.Virginia
WIH0304	QUEST MONT CO	Quest:Mont. County Health Dept
WIH0305	QUEST WHITMAN WALKER	Quest:Whitman Walker Clinic
WIH0321	QUEST GEORGETOWN U	Quest (Georgetown U. Med. Ctr.)
WIH0322	QUEST HOWARD U	Quest (Howard U. Med. Ctr.)
WIH0323	QUEST INOVA VA	Quest: Inova Health Sys. Virginia
WIH0324	QUEST MONT CO	Quest: Mont. County Health Dept.
WIH0325	QUEST WHITMAN WALKER	Quest: Whitman Walker Clinic
WIH0401	LA:THE CLINIC FOR WOMEN	Los Angeles:T.H.E.Clinic for Women
WIH0402	LA:AHF	Los Angeles:AHF
WIH0403	LA:TRI CO SANTA BARBARA	Los Angeles:Tri County Santa Barbara
WIH0404	LA:DREW MLK OASIS	Los Angeles:Drew Med. Ctr. MLK Oasis
WIH0405	LA:PACIFIC OAKS	Los Angeles:Pacific Oaks Med. Ctr.
WIH0406	LA:U. of Hawaii	Los Angeles:U. of Hawaii
WIH0407	LA:Prototypes	Los Angeles:Prototypes
WIH0408	LA:W.A.R.N.	Los Angeles:W.A.R.N.
WIH0409	LA:MATERNAL CHILD	Los Angeles:Maternal Child HIV Mgmt.Ctr.

BBI Code	Site Name	Location
WIH0410	LA:5P21 HIV Clinic	Los Angeles:5P21 HIV Clinic
WIH0411	LA:FAMILY PLANNING	Los Angeles:Family Planning Clinic
WIH0412	LA:Pap Clinic	Los Angeles:Pap Clinic
WIH0420	LA	
WIH0421	LA:THE CLINIC FOR WOMEN	Los Angeles:T.H.E.Clinic for Women
WIH0422	LA:AHF	Los Angeles:AHF
WIH0423	LA:TRI CO SANTA BARBARA	Los Angeles:Tri County Santa Barbara
WIH0427	LA:Prototypes	Los Angeles:Prototypes
WIH0429	LA:MATERNAL CHILD	Los Angeles:Maternal Child HIV Mgmt.Ctr.
WIH0501	SF:E. Bay AIDS Ctr.	San Francisco:E. Bay AIDS Ctr.
WIH0502	SF:HIGHLAND	San Francisco:Highland Hospital
WIH0503	SF:U. of CA @ S.F.	San Francisco:U. of CA @ S.F.
WIH0504		San Francisco:S.F. General Hospital
WIH0521	SF:E. Bay AIDS Ctr.	San Francisco:E. Bay AIDS Ctr.
WIH0522	SF:HIGHLAND	San Francisco:Highland Hospital
WIH0523	SF:U. of CA @ S.F.	San Francisco:U. of CA @ S.F.
WIH0524	SF:GEN	San Francisco:S.F. General Hospital
WIH0601	Chicago Cook County Hospital	Chicago Cook County Hospital
WIH0602	Northwest Memorial Hospital	Northwest Memorial Hospital
WIH0603	RUSH PRESBY ST LUKES	Rush Presbyterian St. Lukes Med. Center
WIH0604	RUSH PRESBY U IL CHICAGO	Rush Presbyterian:U. of Ill. @ Chicago
WIH0621	Chicago Cook County Hospital	Chicago Cook County Hospital
WIH0622	Northwest Memorial Hospital	Northwest Memorial Hospital
WIH0623	RUSH PRESBY ST LUKES	Rush Presbyterian St. Lukes Med. Center
WIH0624	RUSH PRESBY U IL CHICAGO	Rush Presbyterian:U. of Ill. @ Chicago

Appendix C. Fields for Display Tab and Corresponding Operator and Value Selections for Search Tab

	Fields	Operator	Value	***Notes***
1.	Study ID	=	WOMENS INTERAGENCY HIV STUDY	This must be used in all reports for WIHS
2.	Date Received	=	MM/DD/YY OR MM/DD/YYYY	Type the date the shipment was received by Precision. This date is reported on the shipment's *Confirmation of Shipment Received* or *Discrepancy Report* sent by Precision. No leading zeroes
3.	Center	=	See Center Code list on page 3.	Type the center code exactly as it appears in the list. Make sure all center codes used by your site are included in this value.
4.	Subject ID	=	(The WIHS ID)	Search by this only if you know the WIHSID.
5.	Visit	=	XXX	Visit number in 3 digit format with leading zeroes
6.	BSI ID	=	(The BSI ID)	Search by this only if you know the BSI ID.
7.	Freezer			Freezer where vial is stored
8.	Rack			Rack in the freezer where vial is stored
9.	Box			Box in the rack in the freezer where vial is stored
10.	Row			Row # in the box
11.	Col			Col # in the box
12.	Material Type	=	(The type of specimen)	Search by this only if you are looking specifically for serum, plasma, CVL, etc. To see all Material Types possible, click the Code Lists Tab>Material Type>View.
13.	Material Modifier	=	(Further specification of a material)	Not a recommended search field.
14.	S Code	=	(A number code)	See MOO Section 10 for S Code types.
15.	Sample Modifiers			If your text file has a value in this field, read the Codes Lists for this field to find out more about the sample.
16.	Warning			If your text file has a value in this field, read the Codes Lists for this field to find out more about the sample.

Appendix D. DAIDS Repository Policies and Recommended Procedures for Receipt and Distribution of Specimens

1. PRE-APPROVALS REQUIRED
    a. Use of the DAIDS repository must be pre-approved by the DAIDS Repository Project Officer, Mike Ussery. Information required to be submitted includes at a minimum:
        i. Study description including Site collection and processing procedures
        ii. Purpose of study
        iii. Purpose of stored specimens
        iv. Materials to be stored/ processed
        v. Anticipated size of collection
        vi. Expected duration of storage
        vii. Expected accrual/specimen requisition rates
        viii. Sample Informed Consent(s)
    b. Shipping Manifest and Vial Label formats must be submitted to the repository for pre-approval of format before use (see requirements below).
    c. The repository Institutional Review Board must review and approve all study and sub-study protocols, including sample informed consents, prior to the submission of any specimens to the repository.

2. COMMUNICATIONS
    a. The DAIDS repository has a common email address that must be used for all repository correspondence. This address is daids@precisionformedicine.com.
    b. The DAIDS Repository Project Officer, Michael Ussery, may be reached by email at mussery@niaid.nih.gov. The current DAIDS Repository manager at Precision Bioservices is Corinne Scully (corinne.scully@precisionformedicine.com).
    c. Contact information for the repository is as follows:

        DAIDS Repository
        Precision Bioservices
        8425 Progress Drive
        Frederick, MD 21701
        Phone: (301) 668-8100
        Fax: (301) 668-3416

    d. Shipment notifications must be sent to the repository at daids@precisionformedicine.com and our 24 hour emergency contractor, ChemTel Inc., at BBIBIOTECH@chemtelinc.com prior to shipment.
    e. Issues associated with use of the Repository Specimen Management Database System, the BSI-II, should be directed to "BSI Support" at Information Management Services (IMS), Inc., the repository subcontractor responsible for developing, upgrading, and maintaining the BSI-II. IMS technical support staff may be reached via phone at (301) 680-9770 or via email at bsifeedback@imsweb.com. Responses to inquiries that can not be addressed immediately will be made within one business day.

3. SHIPMENT ACCEPTANCE CRITERIA
    a. They must be part of a DAIDS approved study/trial and the DAIDS Repository Project Officer must have approved the use of repository resources for the study/trial.
    b. Shipment notifications must be sent to the repository at daids@precisionformedicine.com and our 24 hour emergency contractor, ChemTel Inc., at BBIBIOTECH@chemtelinc.com prior to shipment. Information required in the pre-notification must include the following information:

i. Shipment Type (i.e., Ambient, Dry Ice, LN2)
ii. Study ID
iii. Study Specific Shipment Number, if applicable.
iv. Center submitting the specimens
v. Courier
vi. Courier Tracking Number
vii. Date Shipped
viii. Expected Arrival Date
ix. Address and contact information for Shipper
x. Address and contact information of the intended recipient
xi. Estimated volume
xii. Dangerous goods classification (i.e., Diagnostic Specimens, Dry Ice)
xiii. Estimated Volume or Quantity of each Dangerous Good
xiv. Estimated number of Specimens
xv. An electronic copy of the shipping manifest in a pre-approved format.

c. Shipping manifests must be submitted electronically with the shipment notification in a pre-approved format. A paper copy of the manifest must also be placed in the shipping container, between the secondary and tertiary packaging. *Minimum information required includes:*
   i. *Unique Identifier:* This identifier must be unique amongst all specimens in the repository (across groups) and must correspond to a unique identifier that is printed on the specimen label in a bar-code and in human-readable form.
   ii. *Study ID/Protocol Number*
   iii. *Patient ID/Participant ID/Subject ID*. This is the identifier by which the person is known in the study/trial.
   iv. *Visit Number*
   v. *Visit Date*
   vi. *Material description* that includes at least material type (i.e., serum, plasma, PBMCs) and preservative/tube type (i.e., heparin, ACD, EDTA, SST). Additional specimens properties captured at the time of preservation (i.e., viability) should also be provided, if these are available.
   vii. *Volume of material and volume unit*
   viii. *Location in the shipment* (box, row and column)
      - Row 1/column 1 should be the vial located in the bottom left corner of the box.
   ix. *Warning/Improper Condition:* This field would only be populated for specimens that had unwanted properties associated with them (i.e., previously thawed, hemolyzed, processing after time specified by protocol)

d. Shipping systems used to submit specimens to the repository must meet the appropriate Department of Transportation and the International Air Transport Association regulations for shipping of biological materials and/or infectious substances.
   i. www.dot.gov/regulations.html
   ii. www.iataonline.com.

e. Freezer boxes that are capable of being stored at ultra-low temperatures must be used for all frozen sample submissions. The acceptable footprint of a freezer box is 5.25 inches x 5.25 inches. Box height must not exceed 3.7 inches unless prior approval from the repository has been obtained. The vendor recommended by the repository for appropriate freezer boxes is Cryo Associates (301-279-2864).

f. Vials rated for storage in the vapor phase of LN2 must be used for all specimens that will be stored at or below-80^{o}C. Refer to Section 8 for a list of recommended shipping materials, vial storage boxes, vials, and labels.

g. Label Requirements
    i. Each study/trial must develop a standard label that will be used across sites participating in a study/trial. This standardized label must be presented to the repository prior to use for confirmation of suitability and legibility.
    ii. Specimen labels must be able to withstand ultra-low temperature storage, <-150^{o}C, without compromising their integrity. Integrity includes legibility of printed information and proper fixation to the vial. The thermal transfer label used and recommended by the repository is Brady Corporation, THT-461. The vendor recommended by the repository is Anthony-Lee Associates (301-670-6100). Refer to Section 8.
    iii. Specimen vials must have computer generated labels. No hand-written corrections to the information printed on the vial labels will be accepted unless they are performed using a black, fine-point, permanent ink sharpie and proper documentation techniques are used for the correction (single line cross out, initial and date).
    iv. Labels must contain a unique identifier that corresponds to the unique identifier on the shipping manifest. This identifier must be embedded in a scannable bar-code and printed in human-readable form.
    v. It is recommended that only essential information be put on a vial label. In most studies this would be only the unique identifier and a material description/code for processing staff to use while they are aliquoting the material into the cryovials.
    vi. It is recommended that the site preserving the specimens perform a quality check on the labels before use on a vial. This quality check should include verification that the bar-code will scan and verification that all information printed on the label in human readable form is present, correct, and legible.
    vii. It is recommended that the study assign the unique identifiers in a randomized fashion so that no information may be ascertained through the identifier (i.e., site of collection) and that a random 10% of the identifiers be reserved for future insertion of QC vials.

h. New Specimen Types within a Study Group for Repository Receipt and Storage
    i. When a new specimen type is being planned by a Study Group for storage at the Repository, the Study Group Specimen Manager must provide a written request to the DAIDS Project Officer and the Repository Management team 60 days in advance that includes all necessary information to ascertain whether the Repository has the capability and resources to store the new specimen type. Information shall include:
        - specimen material type (e.g., hair, blood spots, etc.),
        - preservative/tube/medium type,
        - the Site collection and processing protocol,
        - expected conditions for Repository storage,
        - anticipated utilization schedule for the new specimen type (including short, moderate, long term storage needs),
        - the sample informed consent for collection of the new specimen,
        - total number of specimens to be received by the repository,
        - number of sites that will ship the new material type,
        - and timelines for specimen receipt.
    ii. The DAIDS and Repository Management will review the request and respond in writing to the Study Group Specimen Manager within 2 weeks following the written request submission.
    iii. Upon approval of a request, additional information and/or planning may be required at that time including submission of the revised shipping manifest and examples of the vial labels to be utilized.

4. SHIPMENT REJECTION CRITERIA
    a. Specimen batches that have a high number of discrepancies between the information presented on the specimen vial versus the electronic manifest will be rejected by the repository. A discrepancy that qualifies for the rejection criteria is generated each time:
        i. the information on the vial label does not match the information on the vial manifest or the information is illegible;
        ii. the color/turbidity of the specimen is not consistent with the material reported on the vial label and the manifest;
        iii. if information that should be on the vial label is missing; and/or
        iv. the label is not computer generated or affixed appropriately to the vial.
    b. Shipments containing greater than 1000 vials may have no more than a 1% discrepancy rate. Shipments that contain fewer than 1000 vials may have no more than 5%, or no greater than 15 vials, with discrepancies.
        i. Volume discrepancies will not be included in rejection criteria since these are currently handled via entry of both site recording and repository estimates in the repository inventory database.
        ii. Location discrepancies will not be included in the rejection criteria as long as the vial is in a location that is in the same electronic shipping manifest since we will still be able to match the specimen to the correct data record using the unique identifier.
    c. All shipment batches that are rejected will be returned to the site that submitted the specimens to the repository. The sites would then be responsible for taking appropriate corrective actions and instituting preventive measures in their processes to ensure that the same problem does not occur in the future.

5. REQUISITION POLICIES
    a. All specimen requests must be made via the BSI system.
    b. Each study/clinical trial group must have a person(s) dedicated to creating specimen requests via our inventory control system, the Biological Specimen Inventory system (BSI). Before requisition privileges are granted, the person(s) must be approved by the NIAID Project Officer in advance as well as undergo training in the use of the BSI system.
    c. If any problems are encountered in creating requisitions that are thought to be a problem with the database, these should be directed to BSI-2 support at IMS via phone number at (301) 680-9770 or via email at bsifeedback@imsweb.com. If the problem is thought to be of another origin, contact the DAIDS repository via email at daids@precisionformedicine.com or via phone at (301) 668-8100.
    d. Prior to creating a requisition in the BSI, a withdrawal form that summarizes the request must be submitted via the BSI-web. The address of this website is https://web.bsi-ii.com/login.php. The system will generate a Withdrawal ID that must be entered when creating the requisition in the BSI.
        i. Requisitions that should not have a withdrawal batch associated with them (i.e., an investigation only request) must have a justification entered in place of the Withdrawal ID when a requisition is created in the BSI.
    e. Requests for last vials of a particular material type for a particular participant draw date must specify that “permission for use of the last vial has been granted.” Use of a last vial is granted by the Study Group and the NIAID Project Officer.
    f. Complete instructions regarding the tasks that are to be performed on a vial (i.e., aliquot volumes required, shipment locations), must be provided at the time that the requisition is submitted to the repository.

g. The time taken for data reconciliation can greatly delay shipment requests. In order to minimize the impact on testing laboratories the DAIDS repository has adopted a discrepant vial policy for requisitions. This policy states:
    i. Any vial found to be discrepant upon retrieval for a shipment or aliquot request will be pulled.
    ii. During the double check of the specimens, the discrepancy will be verified and then the vial would be quarantined into a separate box for later data reconciliation. This would be accomplished by applying a return to inventory task in the BSI, which allows for new location to be defined (note that we already have established QC procedures for verification of the location so tracking will not be an issue).
    iii. Vials that were not found to be discrepant would be shipped or aliquoted. Discrepant vials would be placed into a new freezer location.
    iv. A list of discrepant vials would be sent to the Study Group Specimen Manager(s) (SGSMs) for each ship request. The SGSM would collate the discrepancies and include them in new requisitions for shipment or aliquot at a later date (those that can be resolved) or for further investigation. If the discrepancy is severe (i.e., wrong PID) the specimens (and sister vials with same problem) would be destroyed, upon review and approval of the Study Group and NIAID Project Officer.
    v. If the testing requires that samples be grouped in a specific manner, requiring that the process outlined above not be followed, the SGSM would be required to state "Procedure for discrepant vials may not be followed. All Discrepancies must be resolved prior to shipment (or aliquot)", in the task instructions.
    vi. This procedure would apply to all discrepancies found with the exception of the discrepancies that fall within the approved guidelines for each Study Group.

h. All requests for investigations must be made by requesting the specimens in the BSI and adding a task of investigation. The instructions provided for these requests must contain clear, concise descriptions of the issues being investigated.

i. Shipments requiring an overnight courier will be sent only Monday- Wednesday unless there are special circumstances. The repository will include a return airway bill so that the container may be returned to the repository.

6. SUPPLY REQUESTS

a. The DAIDS repository will supply approved studies with appropriate freezer boxes, shipping systems, shipping labels and return airway bills for specimens to be submitted to the repository. All supply requests must be sent via email to daids@precisionformedicine.com. Seven to 10 days are required to process request and ship materials.

7. QUALITY ASSURANCE AND STUDY GROUP SATISFACTION

b. If Study Group Specimen Managers or Site Laboratories have questions or issues regarding the quality of Repository operations or specimens being stored or shipped, please send an e-mail to the following Repository group distribution email address: daidsquality@precisionformedicine.com . Responses to inquiries will be made within 48 hours either via e-mail or phone contact.

c. Specimen requests sent from the repository will be accompanied by a Customer Satisfaction survey. We ask that you please complete this survey and return it to the repository so that we may continually improve the operation of the repository. These surveys should be returned via email at daidsquality@precisionformedicine.com or via fax at (301) 668-3416.

8. RECOMMENDED MATERIALS FOR SITES TO SHIP AND STORE SPECIMENS AT THE DAIDS REPOSITORY
   1) Acceptable Cryovials:
      a) Only vials designed to withstand temperatures down to –195°C are acceptable for use in the DAIDS repository. Below is a list of common cryovials:
         i) Nunc brand CryoTube
            (1) Internally threaded
               (a) Self Standing

Description	Bottom	Capacity	Catalog #
Star foot	Round	1.8 ml	377267
Skirted	Round	1.8 ml	368632
Star foot	Round	3.6 ml	379189
Star foot	Round	4.5 ml	379146
Skirted	Conical	1.0 ml	366656
Star foot	Conical	1.0 ml	377224

               (b) Non-Self Standing

Description	Bottom	Capacity	Catalog #
Plain	Round	1.8 ml	363401
Plain	Round	3.6 ml	366524
Plain	Round	4.5 ml	363452

            (2) Externally Threaded

Description	Bottom	Capacity	Catalog #	Comment
Star foot	Conical	1.0 ml	375353	
Star foot	Conical	1.0 ml	347597	No mark area
Stepneck	Round	1.0 ml	375299	
Stepneck	Round	1.8 ml	340711	
Star foot	Round	1.8 ml	375418	
Star foot	Round	1.8 ml	347627	No mark area
Star foot	Round	4.5 ml	337516	
Star foot	Round	4.5 ml	347643	No mark area

         ii) Nalgene Cryogenic Vials

Description	Bottom	Capacity	Catalog #
Self Standing	Round	1.2 ml	5000-0012
Self Standing	Round	2.0 ml	5000-0020
Self Standing	Round	5.0 ml	5000-0050

iii) Corning

(1) Internally Threaded

Description	Bottom	Capacity	Catalog #
Self Standing	Conical	1.2 ml	430487
Self Standing	Round	2.0 ml	430488
Plain	Round	4.0 ml	430490
Self Standing	Round	4.0 ml	430491
Plain	Round	5.0 ml	430492
Self Standing	Round	5.0 ml	460656

(2) Externally Threaded

Description	Bottom	Capacity	Catalog #
Self Standing	Conical	1.2 ml	430658
Plain	Round	2.0 ml	430661
Self Standing	Round	2.0 ml	430659
Self Standing	Round	4.0 ml	430662
Self Standing	Round	5.0 ml	430663

iv) Sarstedt

Description	Bottom	Capacity	Catalog #	Comment
Self Standing	Conical	0.5 ml	72730106	Attached Cap
Self Standing	Conical	0.5 ml	72730005	
Plain	Conical	1.5 ml	72692005	
Self Standing	Conical	1.5 ml	72694005	

2) Freezer Boxes

a) Freezer boxes that are capable of being stored at ultra-low temperatures must be used for all frozen sample submissions.

b) Freezer box must be 5.25” x 5.25” and the height must not exceed 3.7” without prior approval.

c) Recommended Vendor – CryoAssociates (301-279-2864)

Description	Capacity	Catalog#
3.5” box	81 – 3.5” vials	BX-2-D/D-81
2.0” box	81 – 2” vials	BX-3-D/D-81

3) Cryovial Labels

a) Recommended label type – Thermal Transfer

b) Recommended Vendor – Anthony Lee Associates (301-670-6100)

Catalog # THT-461

4) Shipping Containers

Description	Vendor	Catalog#
Army Shipper	HGI Skydyne	FSSU-24
Foil Bag (for Army Shipper)	Heritage	SP4000
STP-310	Safetypak	STP-310
2” bag combo	Safetypak	STP-710
3” bag combo	Safetypak	STP-730
AirSea 424	AirSea of Atlanta	424
LN2 Dry Shipper	MVE	10777411