WOMEN'S INTERAGENCY HIV STUDY
SECTION 11: DATA MANAGEMENT SYSTEM & PROCEDURES

A. APOLLO

Apollo, the web-based data management system implemented at the beginning of Visit 15, is centrally based; that is, the programming code and data are stored in a central location at WDMAC and accessed by the sites through Internet Explorer. Apollo is used for:

- Data entry
- Data modification
- Report generation
- Tracking study forms
- Creating ***Visit Control Sheets*** (VCS) for upcoming appointments
- Tracking substudy information

Apollo forms have been designed to be similar to the paper versions to lessen the learning curve for the sites and facilitate data entry. While data will be stored centrally, the user interface will be familiar to most computer users and commonly used mouse and/or keystroke combinations are utilized in the system.

Notification of scheduled downtime for system updates/fixes is emailed to all site data managers. Each site will be responsible for disseminating this information to their subsites.

In case of a server failure or loss of Internet connection to outside sites, WDMAC will notify each site's contact person, providing information on any problems and the status of the fix. Each site will be responsible for disseminating this information to their subsites.

1. SYSTEM REQUIREMENTS

   The Apollo system requires Internet Explorer 5.5 (IE5) or 6.0 (IE6) web browser and (preferably) high-speed Internet access. Sites should only use the browser recommended by WDMAC; upgrading to a browser beyond Internet Explorer 6 may cause unexpected problems using Apollo.

2. ACCESSING APOLLO

   Apollo may be accessed from **https://statepiaps.jhsph.edu/apollo/studies/wihs/webroot/html/**, where you will be asked to log into the system. Please note that you must use a secure web browser (128-bit) to access the site.

   In the **Enter Network Password** window (see **Figure 1**), enter your WDMAC-assigned userid and password in the appropriate fields. Some users may find it necessary to enter **statepiaps** in the Domain Field. Click on **OK** to go to the Navigation menu. For security reasons, do not click on "Save this password in your password list." If you have trouble logging in, contact WDMAC.

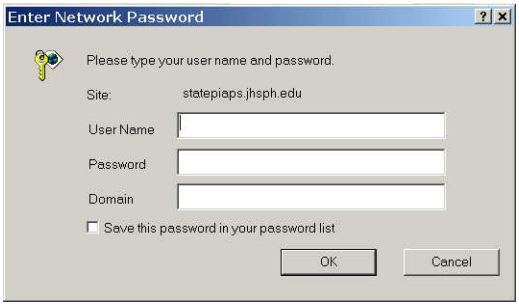

Figure 1

3. NAVIGATION MENU

The Navigation Menu provides access to all aspects of Apollo, including data entry/editing and report generation. The following table gives a brief description of each option in the Navigation Menu:

Menu Item	Description
Home	Displays a brief description about Apollo, the WIHS and WDMAC.
Data Menu	Allows you to view, enter or modify data; download data; add new WIHSIDs; and submit SQL queries on edited data.
Report Menu	Provides a list of reports in Apollo, separated into three categories: Quality Assurance, Participant Monitoring, and Miscellaneous.
Report Bug	Report bugs and suggest changes to Apollo on a WDMAC-reviewed bulletin board.
User Tasks	Priority list of new features to be developed for Apollo.
WDMAC Admin	WDMAC-only access for Apollo administration.
DM Admin	Apollo administrative functions for Data Managers.
WIHS Admin	Link to the WIHS Administrative web site. Specific sections of the website are listed.
Form List	Link to the WIHS Administrative web site page with visit-specific forms.
Codebooks	Link to the WIHS Administrative web site page with visit-specific codebooks.

4. ENTERING AND SUBMITTING DATA

Apollo uses a form entry system that displays each form in its entirety. For forms larger than the screen display, scroll bars at the right and bottom of the screen may be used to view the entire form.

Sections of forms that require entry of repeating data (e.g., descriptions of each of five pregnancies) are entered on subforms (e.g., F23s1), which are linked from within the main data entry form. Subforms allow for multiple records per WIHSID and visit with SEQID as the primary key.

The data entry screens are designed to be similar to the paper versions of forms to facilitate data entry.

In each form, WIHSID, visit, version date, data entry person and date of data entry will be automatically filled in by Apollo. Data entry person and date of data entry are not on the paper forms, but are recorded in Apollo.

a. Field Scrolling and Record Entry

Movement between fields on a form can be done using either the TAB or ENTER keys. Note that using the ENTER key will not enter (or save) the form – that can only be done by clicking on **Submit Data** button at the bottom of the form. A form cannot be saved unless all fields have been filled in; Apollo will not allow blanks in fields on any data entry form except the ***Acertainment Tracking Checklist*** (ATC).

b. Skip Patterns

Apollo has skip patterns programmed into it to match those on the paper forms. When a skip pattern moves from one field to another, skipped fields are automatically filled with "-1" (exception: ***OP14*** uses "-91"). If data have been collected in a section that should be skipped, or if there is an error in the skip pattern, the user can still enter data into fields that were

skipped, using the mouse or tab key to position the cursor in the appropriate field and enter the data.

c. Field-Level Validation

There are many field-level validations that have been developed for Apollo. These are:

- Many forms require that each record be unique. Duplicate records will generate error messages when the record is submitted to the database. A duplicate record based on key fields will not be placed in the database.
- Apollo will not permit blanks to be left in any field on any data entry form except ***ATC***. The user will not be able to save a record until all fields have been filled out. This will require data entry personnel to use "-7" (Refused), "-8" (Don't Know), or "-9" (Missing) to indicate absent data (***OP14*** uses "-97", "-98", or "-99").
- Dates and times are not automatically filled with "/" and ":" characters, which must be entered along with the numbers. An invalid date or time entry will bring an error message box to the screen informing the user to enter dates in a valid mm/dd/yy or hh:mm format; choosing **OK** will allow the user to re-enter the field entry. A shortcut for entering a time is using a period (.) instead of a colon (:) in the time field; the time entry must have two numbers before and after the period.
- Entering an invalid format (e.g., too many digits, letter instead of number) in a field will bring a Type Conversion Error message to the screen. Choose **Yes** to discard the newly entered value and re-enter the data into the field.
- Categorical variables (that is, where response is 1, 2, ...) have been supplied with soft validations. Thus, upon an invalid entry, a validation error box will open informing the user that the value is outside of the specified range. By selecting **Re-Enter Value**, the user can re-enter the field's value. By selecting **Override**, the user can choose to keep the original value, which will be logged in the system. Apollo will open a printable screen listing all such values when the **Submit Data** button is pressed. Once printed, this list can be sent to the appropriate personnel for resolution. Once the appropriate personnel have responded, you can:
    1. Use the **View Data in Form Format, Go to Update Screen** (button at bottom of screen) option to access the record and modify the value to within range.
    2. Use the **Confirm Edit** option on the data menu to confirm an out-of-range value.

Validations after data entry of the entire form, cross-form validation, and longitudinal validation of forms within an individual WIHSID are not currently implemented in Apollo. Much of the cross-form validation and longitudinal validation of forms will be done centrally. An advantage of batch edits is that they provide a better understanding of the most frequently generated edits, which will allow WDMAC to work with sites to avoid the errors during the time data are collected.

To add a record to the database, use the **Submit Data** button located at the bottom of the form. You **must** receive the confirmation message **"Record Successfully Added"** after submitting the record to ensure the data have been saved to the database. If you do not receive this message, the record was not added to the database and you should report this to WDMAC.

After the data have been submitted, use one of the buttons located at the bottom of the form to continue:

Enter Another Record	Begin entry for a new WIHSID on the same form.
Go to Next Form	Return to Enter Form screen, keeping the visit and form preselected on the screen.
Go to Menu	Return to Navigation Menu.
Go to Next Form Screen	Return to Enter Form screen, keeping the WIHSID and form preselected on the screen.

If you choose one of the above options before submitting the record, a message appears, *"Form data has not been saved. Press OK to return to the form or CANCEL to exit without saving data."* The user may choose to save the form or continue without saving the data.

5. VIEWING OR MODIFYING DATA

There are two ways to view and modify the data in Apollo from the data menu. To view and/or modify existing data, select **View Data in Form Format** from the data menu (preferred method). To modify existing data, select **Modify Data** from the data menu. Then, select the form, WIHSID and visit of the data you are interested in. The form will be opened with the relevant data in it. If more than one record was retrieved, you will be able to navigate through the records using the following buttons at the bottom of the form:

- << Go to the first record
- < Go to the previous record
- > Go to the next record
- >> Go to the last record

View Data: To change data from this screen, select the **Go to Update Screen** button to display a tabular format displaying question number, variable name, and existing value for each field. Modify any fields that need to be changed. When you have finished modifying fields, click the **Update** button. Answer **OK** to the "Update this record?" prompt. A prompt with the updated variable name will be displayed for each variable changed. A prompt that says "Record Successfully Updated" indicates the changes have been saved in the database. If you do not receive this message, you should assume the changes have not been saved and notify WDMAC of the error. **This is the preferred method for updating data in Apollo.**

Modify Data: To change data in this screen, type the new values and click **OK** on the change notification message. When you have finished modifying fields, click the **Update** button. Answer **OK** to the "Update this record?" prompt. A prompt with the updated variable name will be displayed for each variable changed. A prompt that says, "Record Successfully Updated" indicates the changes have been saved in the database. If you do not receive this message, you should assume the changes have not been saved and notify WDMAC of the error.

To change a value in a primary key field, such as VISIT, contact the data manager at WDMAC by email or telephone. Only WDMAC is able to update primary key fields.

All forms from Visit 12 onward will be available in Apollo.

All data from earlier visits (prior to the current visit) will be available in the historical database provided to the sites semiannually by WDMAC.

Deleting Data: Historical data (i.e., data that have been centrally edited by WDMAC) cannot be deleted by the sites. Please contact the data manager at WDMAC by email or telephone to request deletion of a historical record. Current visit data (i.e., dirty data) may be deleted at the site level.

6. DOWNLOADING DATA

   a. To download data to your local computer, select "Download Data to a separate mdb file" or "Download all tables to one mdb file" from the data menu. Then, select the form, WIHSID(s), visit(s) and variable(s) in which you are interested. The more restrictive your criteria, the less time the download will take. In the future, files will be compressed to further reduce download time.

      Data from individual forms may be downloaded from Apollo in MS Access format, with additional file formats becoming available at a later time. Summary files and historical freezes are not included in Apollo but are provided separately by WDMAC to the sites.

      All download requests will be logged.

   b. A SQL query may also be run on the data in Apollo to review a few records or fields in a table. This feature allows a user with a basic knowledge of SQL query language to quickly review fields in a table for one or two participants. Requesting too much information through this feature may have an adverse impact on Apollo's speed; WDMAC requests that examination of complete visit records in a table continue to be performed through the download feature.

7. REPORTS

   To run a report, select the Report Menu link. There are three tabs separating the reports into different areas of monitoring: Quality Assurance, Participant Monitoring, and Miscellaneous. After clicking the relevant tab, select the report that you are interested in viewing. Some reports may require you to enter additional data, such as WIHSID and/or visit, before they are run.

   The following reports are available in Apollo:

   a. Quality Assurance Reports

      1. ***Form Status Report****:* Displays information about WIHSID, VISIT, FORM Name, *CODE (status information), and REASON; (* C = Completed; M = Missing; E = Expected; NA = Not Expected). Web users can select single and multiple forms, WIHSIDs, VISITs, and status to get the form status report.

      2. ***Glucose Tolerance Test or DXA Scan Not Complete****:* Shows date of DXA scan and date blood drawn for OGTT for each WIHSID and VISIT of participants enrolled in the *Metabolic Substudy*.

      3. ***Medical Record Abstraction Report****:* Includes three sub-reports:

         a) Abstraction not completed: Displays ascertainment disposition in ATC, when disposition has not been completed (i.e., disposition not in 1, 2, 3, 4, 5, 6, 7 or 8) for each WIHSID.

         b) Abstraction complete, confirmed: Displays events confirmed via ascertainment (i.e., WEA_AT = 1) in ATC for each WIHSID.

         c) Abstraction complete, not confirmed: Displays events not confirmed via ascertainment (i.e., WEA_AT = 2) in ATC for each WIHSID.

      4. ***Missing Form Report****:* Displays information about missing FORM Name, WIHSID, VISIT, and REASON.

5. ***Missing PK Time Points Report:*** Includes three sub-reports:

   a) Missing time points in Group A collection: Displays time of blood draw for missing collections from PK05A.

   b) Missing time points in Group B collection: Displays time of blood draw for missing collections from PK05B.

   c) Missing time points in Group C collection: Displays time of blood draw for missing collections from PK05C.

6. ***Ascertainment Data Report:*** Includes three sub-reports:

   a) Current abstractable events that have not yet been data entered.

   b) Historic abstractable events that have not yet been data entered.

   c) Entries in ***ATC*** that do not have corresponding ***F22HX, F23*** or ***DENR***: This report catches missed ***ATC*** records during ***DENR, F22HX*** and ***F23*** data entry. The ETN (event tracking number) on the report will point to the ***ATC*** data entry form to allow the user to enter the missed ***ATC*** record entries in ***ATC*** that do not have corresponding ***F22HX, F23*** or ***DENR*** records. Displays WIHSID, VISIT, FORM/QUESTION #, DISEASE CODE, and ETN, which allows user to remove ***ATC*** record or modify ***F22HX/F23/DENR*** record from this report.

7. ***Verification of Substudy Enrollment Window Report:*** Includes four sub-reports:

   a) Sex Seroid Enrollment Window > 90 days: Displays WIHSID, VISIT, date of ***F21*** interview, date of ***SSNOTI*** enrollment, date difference between ***F21*** and ***SSNOTI***.

   b) Intensive PK Enrollment Window > 45 days: Displays WIHSID, VISIT, date of ***F21*** interview, date of ***PKNOTI*** enrollment, date difference between ***F21*** and ***PKNOTI***.

   c) Metabolic Enrollment Window > 63 days for HIV+: Displays WIHSID, VISIT, date of ***F21*** interview, date of ***MSNOTI*** enrollment, date difference between ***F21*** and ***MSNOTI***, and HIV status.

   d) Metabolic Enrollment Window > 94 days for HIV-: Displays WIHSID, VISIT, date of ***F21*** interview, date of ***MSNOTI*** enrollment, date difference between ***F21*** and ***MSNOTI***, and HIV status.

b. Participant Monitoring Reports

1. ***Abnormal Paps and Colposcopy Status Report:*** Displays information about WIHSID, VISIT, ***C60*** (Pap) date, ***C60*** result, ***L14*** (colpo) status, ***L14*** date, number days from Pap to colpo, reason colpo not done.

2. ***ARVs Across Forms Report:*** Displays WIHSID, VISIT, and ARVs reported at selected visit on ***F22MED, DSG, DRUG1*** and ***F29a*** forms to allow comparison.

3. ***CD4/Low CD4 Count Report:*** Includes two sub-reports:

   a) Low CD4 Count Report: Displays information about WIHSID, VISIT, CD4 count <200, Visit DATE, CONTACT DATE, and SPECIMEN DATE.

   b) CD4 Report: Displays information about WIHSID, VISIT, all CD4 count results, Visit DATE, and SPECIMEN Date.

4. ***Enrollment Report for 2001/2002 Recruits****:* This report displays the following information for 2001/02 recruits to the WIHS for both core and the oral substudy:

    a) Enrollment into three groups: HIV-negative, HIV-positive/HAART naïve, HIV-positive/HAART experienced, and total enrollment.

    b) Number of women enrolled by individual site and overall.

    c) Target enrollments (based on grant) by individual site and overall.

    d) Percent of target enrolled by individual site and overall.

    e) Characteristics of women enrolled into the three groups in (HIV-, HIV+/HAART-, HIV+/HAART+):

        - Median, minimum, maximum and Q1 and Q3 age.
        - Number (%) of women over 30 years of age.
        - Number (%) of women reporting IDU.
        - Number (%) of women reporting high risk sex in past year.
        - Number (%) enrolled as White/non-Hispanic; White/Hispanic; Black/non-Hispanic; Black/Hispanic; American Indian/Alaskan Native; Asian; Native Hawaiian/Other Pacific Islander; and Other by site and overall.

5. ***Enrollment Report for 2011/2012 Recruits:*** This report displays the following information for 2011/12 recruits to the WIHS core.

    a) Enrollment into two groups: HIV-negative, HIV-positive, and total enrollment.

    b) Target enrollments by individual site, age category, ethnicity and AIDS status.

    c) Percent of target enrolled by individual site.

    d) Characteristics of women enrolled:

        - Number of women enrolled into each age category by HIV serostatus.
        - Number of women enrolled by race/ethnicity and HIV serostatus
        - Number of women reporting IDU in past year.
        - Number of women reporting high risk sex in past year.
        - Number of women reporting prior AIDS-defining event.

6. ***Participant Transfer List****:* Displays current WIHSID, original WIHSID, and last DATE/VISIT with original WIHSID.

7. ***Retention Report****:* Displays information regarding visits conducted and missed, deaths, active and lost participants, retention rate and attrition rate for each visit by site and serostatus. Report can be run for only the 2001/02 recruits, or for all of WIHS (1994/95, 2001/02, and 2011/12 recruits).

8. ***Substudy Enrollment Report****:* Includes ten sub-reports:

    a) Cardiovascular Enrollment Report: Displays number of women enrolled, BL carotid ultrasounds completed, QA scans completed, number women not enrolled, and fasting CVD specimens collected.

b) Cardiovascular Follow-up Report: Includes four sub-reports:

- Completed Scans First Follow-up: Number of follow-up and QC scans completed during visits 25 through 28.
- Completed Scans Second Follow-up: Number of follow-up and QC scans completed during visits 29 through 31.
- Target Window First Follow-up: Target windows for first follow-up scan by WIHSID.
- Target Window Second Follow-up: Target windows for second follow-up scan by WIHSID.

c) Intensive PK Enrollment Report: Displays enrollment numbers and targets by site for study drugs: Sustiva (efavirenz), Viramune (nevirapine), Kaletra (lopinavir/ritonavir), Viracept (nelfinavir), Reyataz (atazanavir), and Isentress (raltegravir).

d) Metabolic Enrollment Report: Displays enrollment and target totals by site; median ages; race/ethnicity in four groups:

- HIV+, no ART (pre-menopausal).
- HIV+, on HAART (pre-menopausal).
- HIV- (pre-menopausal).
- HIV+ (post-menopausal).

e) Metabolic Follow-up Report: Displays WIHSID, VISIT, enrollment, baseline and follow-up visit dates.

f) Metabolic Follow-up Retention Report: Includes total number of baseline and follow-up visits conducted, number missed visits, and attrition rate.

g) WIHS III Neurocognition Report: Includes three subreports:

- Neurocognition Substudy Compliance: By site and form, lists numbers of forms administered, not administered, completed in full and refused.
- Neurocognition Non-compliance Reasons: For forms not administered or not completed, lists reasons for non completion.
- Neurocognition Enrollment Report: By site, number enrolled and not enrolled in substudy protocol.

h) WIHS IV Neurocognition Report: Includes three subreports:

- NC Battery – Waves 1 & 2: By visit, site and form, lists numbers of forms administered.
- One-time NC Forms: By site and form, lists numbers of forms administered for selected NC forms that are to be administered one-time only to participants.
- NC06 by HIV status – Waves 1 & 2: Lists number of NC06 (HVLT-R) forms completed by site and HIV serostatus.
- Target Window for NC Wave 2 Battery: Lists by site, the dates of Wave 1 and Wave 2 (if completed) NC Battery administration, plus the target window (begin and end dates) for Wave 2 administration.

i) PK Enrollment Duplication Report: Displays participants enrolled at two or more visits with the same PK Substudy medication.

j) Pregnancy Protocol Enrollment Report: Displays number of women enrolled with pregnancies, deliveries and terminations by site and visit.

k) Sex Steroid Enrollment Report: Displays *Sex Steroid Substudy* enrollment for HIV+ and HIV- participants for each site.

9. ***Visit Control Sheet*** *(VCS):* Displays the following information for each participant:

a) Participant information: WIHSID, HIV status, presence of cervix, DOB, preferred language.

b) Antiretroviral medication use at most recent prior visit.

c) Visit information: current visit and dates of all prior visits.

d) Substudy enrollment information.

e) Expected study forms and local lab forms for selected visit.

f) Future appointments.

10. ***Visit Report****:* Displays information about the visit dates for each WIHSID. Values are obtained from the VISITS table.

c. Miscellaneous Reports

1. ***Abbreviated Visits and Blood Draws Report:*** By visit and site, lists all WIHSIDs that have completed an abbreviated visit. Also shows where and why the abbreviated visit was completed, the blood draw date (if applicable) and participant HIV serostatus.

2. ***Display Form with Variable Names****:* Displays the data entry form with variable names included.

3. ***General Status Report****:* This report includes information regarding WIHSID, DOB, preferred interview language, HIV status, vital status and cervix status.

4. ***WDMAC Audit Report****:* This report is used solely by WDMAC personnel in the conduct of data audits performed as part of regular site visits.

8. GENERATING/ADDING A WIHSID

In cases of transfers or new study participants, sites will need to register a new WIHSID with Apollo. All new WIHSIDs must use the NERI-created algorithm with a check-digit in the eigth position. To do this, select "Generate New WIHSID" from the Data Menu and enter the first seven numbers of the WIHSID based on site-specified criteria. Select "Generate WIHSID" to obtain the check digit for the eigth character. More than one WIHSID may be generated during this process. After the WIHSID has been generated, you may click "Add WIHSID" to add the WIHSID to Apollo or select "Add New WIHSID" from the data menu and enter the new WIHSID manually. Do not enter the WIHSID with hyphens, dashes or spaces in the field. Apollo will not accept a new WIHSID that does not fit the required algorithm.

9. OUTCOMES

The outcomes ascertainment tracking system works differently and more simply in Apollo than it did in the WDMS. The ***ATC*** and ***ACS*** forms and report have been merged into a single form, named "***ATC***."

When an event is logged (via ***F22HX, F23*** or ***DENR***), a record will automatically be added to the ***ATC*** table in Apollo that includes a computer-generated tracking number, the event code, event description, WIHSID, visit, the form and question number, HIV status and current and previous visit dates. To fill in the ***ATC*** form with the ascertainment information, bring up the ***ATC*** form through the "Modify" option on the main menu. When you select the appropriate WIHSID and

visit, the relevant event(s) will be brought up on the screen with the information described above. At this time, print out the ***ATC*** form for resolution by ascertainment staff. When the printout is returned with the remaining questions answered, enter those answers into their appropriate fields (that will be blank) by returning to the ***ATC*** form through the "Modify" option. If you have an older ***ATC*** record that is not in the system, you may use the Enter a Form option to add an ***ATC*** form with a pre-existing event tracking number.

If an event is not generated automatically during data entry, use the **Ascertainment Data Report** with **Outstanding ATC Data Entry Report** selected to manually generate the ***ATC*** record for events at visit 17 and later. This report is generated nightly based on records in ***ATC*** and ***F22HX/F23/DENR***.

If an event has been generated through an accidental keystroke during data entry, use the **Ascertainment Data Report** with **Entries in *ATC* that do not have corresponding *F22HX* or *DENR* records** selected to list ***ATC*** records without corresponding responses in ***F22HX*** or ***DENR***. Options to **Modify** or **Delete** the record are displayed.

Beginning with visit 17 ***ATC*** records, the Medical Record Abstraction Report (not complete, compete and confirmed, or complete and not confirmed) is available in the Quality Assurance section of the Reports Menu.

B. SECURITY

It is our intention to ensure the WIHS data are of high quality and secure from external threats. In this section, we detail security mechanisms that Apollo will use to guarantee that WIHS data are not compromised.

1. WINDOWS 2000 INTEGRATED AUTHENTICATION

   Each individual who uses Apollo will require a user account on the WDMAC Windows 2000 Advanced Server. We use group permissions and integrated authentication to control access to the server. Authentication and data entry is encrypted using 128-bit secure sockets layer (SSL) to guarantee that user credentials are not compromised. The SSL security protocol provides data encryption, server authentication, message integrity, and optional client authentication for a TCP/IP connection. It prevents interception of data between the site and the Apollo server.

2. IP ADDRESS RESTRICTIONS

   Access to the web site will be restricted to the IP addresses of computers being used for the WIHS. The data managers have already provided these IP addresses to WDMAC. Only IP addresses registered by site data managers with WDMAC will have access to the system. Users of other computers on the Internet will not have access to Apollo and will be rejected from Apollo with a standard error message. This security element has not yet been implemented.

3. SITE-SPECIFIC DATA ENTRY

   Each registered user will only be able to enter or edit data from his/her site – users will not be able to enter or change data from other sites. Downloaded data may contain data from all sites.

4. PARTICIPANT NAME/WIHSID SEPARATION

   Participant names or other identifying information are never associated with WIHSIDs in Apollo. Confidentiality of participants is guaranteed using the same mechanism that has always been used in the WIHS. No person or computer at WDMAC has access to participant names, and the data is associated only with WIHSIDs.

5. HARDWARE INTEGRITY AND JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH FIREWALL

   WDMAC maintains all of its own hardware within the STATEPI group located in the Department of Epidemiology. System administrator privileges are restricted to a limited number of personnel. Accounts are given only to users who are actively working on STATEPI projects.

   All WDMAC computers are behind the Johns Hopkins Bloomberg School of Public Health firewall. IP address restriction is much safer when the server is run behind a firewall that is capable of detecting and rejecting attempts at aliased IP addresses.

   While no security is foolproof, by using multiple, state-of-the-art security mechanisms, we hope to prevent any intrusions into the WIHS data.

6. SECURITY AT THE SITE LEVEL

   The following items can be done by you to help keep the WIHS data secure:

   - Do not share your username with non-WIHS staff.
   - Do not share your password with anyone, including other WIHS staff.
   - Do not check the "Save this Password" checkbox when logging in to the system.
   - Close your web browser when not using Apollo.

   To enable continuous data entry, data managers must notify WDMAC of new and obsolete IP addresses as soon as possible. Sites should also notify WDMAC of resigning and newly-hired personnel for account management as soon as possible.

C. FORMS

WDMAC will distribute new or updated forms with a new version date by way of a numbered **Communication Memo**. All WIHS forms contain a footer with the date the form was implemented. This date will be considered the current version number of the form. Subsequent changes to forms will be indicated in the footer in two ways:

1. In the case of substantial revision to a form (i.e., a change in the data collected or the addition or deletion of variables), the change will be indicated by assigning a new date to the form. For example, if ***F07*** version 08/15/95 were to receive substantial changes, the version date in the footer would change to the date of implementation of the new version (e.g., <u>from</u> 8/15/95 <u>to</u> 10/01/98).

2. In the case of minor revision to a form (i.e., no change in data collected – correction of typo or change in wording), the change will be indicated by adding a letter after the date in the footer. For example, if ***F07*** version 10/01/98 were to receive minor changes, an "a" would be added to the end of the version date in the footer. If ***F07*** version 10/01/98a were to receive subsequent minor changes, the "a" in the footer would be changed to a "b" (e.g., <u>from</u> 10/01/98 <u>to</u> 10/01/98a <u>to</u> 10/01/98b).

See the ***Form and QxQ Versions*** Excel file distributed at every visit for a listing of all current WIHS form versions.

D. PARTICIPANT IDENTIFICATION (ID) NUMBERS

Participant ID numbers for the WIHS (WIHSIDs) were assigned sequentially when the ***Screening Form*** was filled out. The structure of the WIHSID is as follows:

S - BB-PPPP- C

S:	Site number:	1: NYC (Bronx) 2: Brooklyn 3: Washington, D.C. 4: Los Angeles/Southern California 5: San Francisco 6: Chicago
BB:	Subsite number:	Within each WIHS consortium there are subsites (hospitals/clinics/institutions) that see participants and conduct study visits. During the WIHS start-up phase, Project Directors assigned a subsite number to each subsite within their consortium. (**NOTE:** if an institution considered the "central/primary" site enrolled and conducted study visits, then it was assigned a "subsite" number as well.)
PPPP:	Participant's number:	Participants within each subsite were assigned individual numbers sequentially. (The four-digit ranges for participant numbers expected to enroll at each subsite were also assigned by the respective Project Director.)
C:	Check digit:	For 1994/95 recruits, this is a computer-generated digit. In order to prevent data entry of incorrect WIHSID numbers, the NERI DMS used an algorithm to generate this last digit. For 2001/02 recruits, sites manually assigned any number they wished to the check digit "C" position. Beginning in mid-2004, the computer-generated 8th digit was implemented again to ease use of the LDMS system. For 2011/12 recruits, this is an Apollo-generated digit.

- All **1994/95** recruits have either a "0" (zero) or a "1" as the first digit of the subsite (i.e., S-**0**B-PPPP-C or S-**1**B-PPPP-C).
- All **2001/02** recruits enrolled into the WIHS were assigned an 8-digit WIHSID of the form S-**2**B-PPPP-C.
- All **2011/12** recruits enrolled into the WIHS were assigned an 8-digit WIHSID of the form S-**3**B-PPPP-C.

All sites adding new subsites should use the "BB" digit to identify the new subsites.

E. VARIABLE NAMES AND CODEBOOKS

NERI's variable naming system used duplicate names for variables on different forms. Furthermore, NERI had no convention for naming variables. This made analyses of the data, particularly longitudinal analyses, very difficult. There was also the possibility of overwriting variables when merging datasets.

Rectifying the above problems required a tremendous effort: approximately 5,700 variables on 140 forms had to be renamed. Every new WDMAC variable has six characters; the first four are a unique name for the variable and the last two indicate on which form the variable is located. Therefore, all variable names on a given form have the same last two characters. This naming convention facilitates longitudinal analyses and eliminates the possibility of overwriting variables when merging datasets.

Documentation describing the structure of the new data was created. A Variable Master File (VMF) was created for every form. The VMF file describes, in a structured format, the name, type, length, description, and range of every variable on that form. In addition, the old NERI variable name is included to provide for easy analyses using NERI variable names. A small portion of a VMF file is shown below:

```
Women's Interagency HIV Study
Form 22 - Follow-Up Medical & Health Hx
------------------------------
8 8.0     NERI=ID
WIHSID = Participant ID
A.1 =
10100010= ID# 10100010|.|.|60499999= ID# 60499999
------------------------------
2 2.0     NERI=VNUM
VISIT = Visit number
A.2 =
1= Visit 1|.|.|99= Visit 99
------------------------------
6 $      NERI=FKEY
FKEY = Form identifier number
A.0 =
Character
------------------------------
8 $      NERI=FORM_V
VERSMH= Form version
A.3 =
01/01/94= January 1, 1994|.|.|12/31/99= December 31, 1999
|-1= N.A. (Skipped)|-7= Refusal|-8= Don't know|-9 or Blank= Missing
```

Additional files are generated from the VMF file by WDMAC and distributed with the historical data. These files are listed below with their filename extensions and descriptions.

1. Codebook files, *.cdb, data dictionary
2. SAS input files, *.inp, fixed-column SAS input files
3. Index files, *.ndx, condensed version of codebook file
4. SAS put files, *.put, fixed-column SAS put files

The codebook files are a user-friendly version of the VMF files and are a comprehensive definition of the structure of the data. The columns in a codebook file are listed in order below.

1. Start Column: the column position where the given variable's data begins
2. Field Len: the length of the given variable
3. Field Format: the format of the given variable
4. Variable New: the WDMAC variable name
5. Variable Old: the NERI variable name
6. Section/Question: the location of the given variable on the form
7. Description: description of the data the given variable holds
8. Code: range of possible values for the given variable

WDMAC Form	NERI Form	Tag	Description	Table
ABRV	ABRV	AB	Abbreviated Visit	ABRV
ABRVs1	ABRVs1	AB	Abbreviated Visit (B16: Medication Use)	ABRVs1
ABRVs2	ABRVs2	AB	Abbreviated Visit (D2: Administration Problems)	ABRVs2
ABRVs3	N/A	AB	Abbreviated Visit (B5: Pregnancy History)	ABRVs3
ACS	ACS	AT	Ascertainment Control Sheet	ATC
AMB	N/A	AM	ACSR Ascertainment Tracking Checklist	N/A
ATC	ATC	AT	Ascertainment Tracking Checklist	ATC
BLSA	N/A	AG	Baltimore Longitudinal Study of Aging Questionnaire	BLSA
C30	C30	CA	Toxoplasmosis	C30
C31	C31	CB	HTLV 1&2	C31
C45	C45	CC	Bacterial Vaginosis Smear Gram Stain	C45
C50	C50	CD	Urine for Chlamydia	C50
C51	C51	CE	Swab Confirmatory	C51
C52	C52	CF	HPV by PCR	C52
C53	C53	CM	HPV by Hybrid Capture CVL tube #1	C53
C54	C54	CG	Viral Load	C54
C60	C60	CH	Pap Smear	C60
C65	C65	CI	Syphilis DFA – Genital Ulcers & Fissure	C65
C66	C66	CJ	Laboratory-Serum Herpes Serologies	C66
C70	C70	CK	Laboratory-Stimulated Saliva Evaluation	C70
C71	C71	CL	Laboratory Subgingival Plaque	C71
C72	N/A	CN	Erythematous Candidiasis Smear Results	C72
CA01	CA01	RA	MRA Hospital Information	CA01
CA02	CA02	RB	Surgical Procedures	CA02
CA03	CA03	RC	Endoscopy/Bronchoscopy	CA03
CA04	CA04	RD	Cytology/Pathology/Biopsy	CA04
CA05	CA05	RE	Microbiology	CA05
CA05s1	CA05	RE	Microbiology (B3: Culture Abs)	CA05s1
CA05s2	CA05	RE	Microbiology (C5: Sensitive)	CA05s2
CA05s3	CA05	RE	Microbiology (D2: Culture Results)	CA05s3
CA06	CA06	RF	CT/MRI/ULTRASOUND	CA06
CA07	CA07	RG	Cerebrospinal Fluid	CA07
CNCR	N/A	CN	Cancer Registry Case Report	CNCR
COLPO	N/A	CP	Colposcopy Tracking	COLPO
CONS	N/A	CT	Consent Tracking	CONS
CORE	N/A	CO	Clinical Outcomes Reporting Form	CORE
COREs1	N/A	CO	Clinical Outcomes Rpt (C6: Underlying Causes)	COREs1
COREs2	N/A	CO	Clinical Outcomes Rpt (C6: Other Significant Conditions)	COREs2
CV01	N/A	UT	CV: Carotid Ultrasound Tracking Form	CV01
CV29	N/A	US	CV: Fasting Blood Specimen Collection Form	CV29
CVNOTI	N/A	UN	CV: Participant Notification	CVNOTI
DACS	DACS	DB	Death Abstract Control Sheet	DACS
DATR	DATR	DN	DATRI Enrollment Notification Form	DATR
DENR	DENR	DE	Disenrollment Form	DENR
DRUG1	N/A	D1	Drug Form 1 – Antiretroviral Medications	DRUG1

WDMAC Form	NERI Form	Tag	Description	Table
DRUG2	N/A	D2	Drug Form 2 – Non-antiretroviral Medications	DRUG2
DRUG3	N/A	D3	Drug Form 3 – Hepatitis Medications	DRUG3
DSG	N/A	DS	Antiretroviral Dosage Form	DSG
DSGs1	N/A	DS	Antiretroviral Dosage Form (B1: ART use)	DSGs1
EL	N/A	EL	Eligibility Form (2001/02 &2011/12 Recruits)	N/A
F00	0	SC	Screening Form	F00
F01	1	SD	B/L Sociodemographics	F01
F02	2	MH	B/L Medical & Health Hx	F02
F02s1	2	MH	B/L Medical & Health Hx (F1.C: Med Hx)	F02s1
F02s2	02a	MH	Medication Addendum (F21: Other Med)	F02s2
F03	3	OB	B/L OB/GYN & Contra Hx	F03
F03s1	03a	OB	Pregnancy Addendum	F03s1
F04	4	BH	B/L Alc. Drugs & Sex Behav.	F04
F05	5	HC	B/L Health Care Utilization	F05
F06	6	PS	B/L Psychosocial Measures	F06
F06s1	6	PS	B/L Psychosocial Measures (E4: Deceased child)	F06s1
F06s2	06a	PS	B/L Psychosocial Measures Children Addendum	F06s2
F06s3	6	PS	B/L Psychosocial Measures (Intv assessment)	F06s3
F07	7	PE	Physical Exam	F07
F07s1	7	PE	Physical Exam (C3: Skin lesion)	F07s1
F07s2	7	PE	Physical Exam (D3: Oral lesion)	F07s2
F08	8	GY	Gynecological Exam	F08
F08a	08a	PC	Potential CVL Contaminants	F08a
F08s1	8	GY	Gynecological Exam (B20-39: Abnr Lesion)	F08s1
F09	9	BC	B/L Blood Spec. Coll.	F09
F10	10	PL	Plasma & Cell Separ. & Freezing	F10
F11	11	SP	B/L Spec. coll. During PE	F11
F20	N/A	NR	Baseline History (2001/02 & 2011/12 Recruits)	F20
F20s1	N/A	NR	B/L Hx (C13: Cancer Dx)	F20s1
F20s2	N/A	NR	B/L Hx (D3: Pregnancy Outcomes)	F20s2
F20s3	N/A	NR	B/L Hx (C24: Hepatitis Medication Use)	F20s3
F20s4	N/A	NR	B/L Hx (C31: Head Injury History)	F20s4
F21	21	SD	F/up Sociodemographics	F21
F21s1	N/A	SD	F/up Sociodemographics (B9b-B9c: Hx of incarceration)	F21s1
F22	22	MH	F/up Medical & Health Hx	F22
F22s1	22	MH	F/up Medical & Health Hx (F1.C: Med Hx)	F22s1
F22s2	22	MH	F/up Medical & Health Hx (G1A: Other Med)	F22s2
F22s3	N/A	MH	F/up Medical & Health Hx (F2.A: ARV Hx)	F22s3
F22s4	N/A	MH	F/up Medical & Health Hx (F9: Non-ARV Hx)	F22s4
F22s5	N/A	MH	F/up Medical & Health Hx (F10.B: Comp/Alt Tx)	F22s5
F22s6	N/A	MH	F/up Medical & Health Hx (F14: Other Rx Tx)	F22s6
F22s7	N/A	MH	F/up Medical & Health Hx (F15o: Other Symptoms)	F22s7
F22s8	N/A	MH	F/up Medical & Health Hx (C13: Cancer Dx)	F22s8
F22HX	N/A	MH	F/up Health Hx	F22HX
F22HXs8	N/A	MH	F/up Health Hx (C14: Cancer diagnoses)	F22HXs8
F22HXs10	N/A	MH	F/up Health Hx (C47: Head injuries)	F22HXs10

WDMAC Form	NERI Form	Tag	Description	Table
F22MED	N/A	MH	F/up Medical History	F22MED
F22MEDs3	N/A	MH	F/up Medical History (B2A: ARV Hx)	F22MEDs3
F22MEDs4	N/A	MH	F/up Medical History (C1: Non-ARV Hx)	F22MEDs4
F22MEDs5	N/A	MH	F/up Medical History (F1B: Comp/Alt Tx)	F22MEDs5
F22MEDs6	N/A	MH	F/up Medical History (E13: Other Rx Tx)	F22MEDs6
F22MEDs7	N/A	MH	F/up Medical History (G1s: Other Symptoms)	F22MEDs7
F22MEDs9	N/A	MH	F/up Medical History (D1: Hepatitis Tx)	F22MEDs9
F22r	N/A	DR	2001/02 Recruit ARV History	F22r
F22rs1	N/A	DR	2001/02 Recruit ARV Hx (3: ARV use)	F22rs1
F23	23	OB	F/up OB/GYN History	F23
F23s1	23	OB	F/up OB/GYN History (BC: Pregnancy Hx)	F23s1
F24	24	BH	F/up Alc. Drug & Sex Behav. (v2-24)	F24
F24s1	N/A	BH	F/up Alc. Drug & Sex Behav. (v2-24) (D: sex partners)	F24s1
F24BEH	N/A	BH	F/up Alc. Drug & Sex Behav. (v25+)	F24BEH
F25	25	HC	F/up Health Care Utilization	F25
F25a	25a	HC	F/up Health Care Utilization Supplement	F25a
F25b	N/A	DP	Mental Health Care Utilization	F25b
F25bs1	N/A	DP	Mental HCU (B1: Medication Use)	F25bs1
F26	26	PS	F/up Psychosocial	F26
F26s1	26	PS	F/up Psychosocial (E7: Deceased child)	F26s1
F26a	N/A	PY	Assessment of Physical Functioning	F26a
F26r	N/A	HB	History of Abuse	F26r
F27	27	KF	Karnofsky Scale	F27
F27s1	27	KF	Karnofsky Scale (SEC_Q, Problem)	F27s1
F29	29	BC	F/up Blood Spec. Collection Form	F29
F29a	N/A	BI	F/up Antiviral Usage Assessment for Blood Draw	F29a
F29as1	N/A	BI	F/up ARV (1a: ARV use)	F29as1
F29as2	N/A	BI	F/up ARV (2a: Date/Time taken)	F29as2
F29r	N/A	BR	B/L Blood Spec Collection (2001/02 & 2011/12 Recruits)	F29r
F31	31	SP	F/up Spec. Collected During PE	F31
F31a	N/A	HR	Hair Color, Texture, Tx History	F31a
F31r	N/A	SR	B/L Spec Coll During PE (2001/02 & 2011/12 Recruits)	F31r
F7r	N/A	PR	PE Addendum (2001/02 & 2011/12 Recruits)	F7r
F7rs1	N/A	PR	PE Addendum (B3: Skin lesion)	F7rs1
F7rs2	N/A	PR	PE Addendum (C3: Oral lesion)	F7rs2
FLU01	N/A	F1	Influenza Substudy: Enrollment Form	FLU01
FLU02	N/A	F2	Influenza Substudy: Monthly Follow-up Questionnaire	FLU02
FLU03	N/A	F3	Influenza Substudy: Blood Specimen Collection Form	FLU03
FLU04	N/A	F4	Influenza Substudy: Medical Record Abstraction	FLU04
FSFI	N/A	FS	Sexual Functioning Index	FSFI
HPVKAB	N/A	HP	HPV Knowledge and Attitudes	HPVKAB
HVNOTI	N/A	HN	HHV-8 Recruitment Outcome Form	HVNOTI
HVDENR	N/A	HD	HHV-8 Disenrollment Form	HVDENR
HX	N/A	HX	Family and Personal History	HX
HXs1	N/A	HX	Family and Personal History (A5: Family Cancer Dx)	HXs1
INT	N/A	IN	Interim Events Form	INT

WDMAC Form	NERI Form	Tag	Description	Table
INTs1	N/A	IN	Interim Events Form (A4: Cancer Dx)	INTs1
L01	L01	LA	HIV ELISA & Western Blot	L01
L02	L02	LB	Serum-Hepatitis	L02
L03	L03	LC	Automated CBC/Differential	L03
L03a	L03a	LD	Hand-Manual Differential	L03a
L04	L04	LE	Flow Cytometry	L04
L05	L05	LF	Liver/Renal Function Tests	L05
L06	L06	LG	Serum-Syphilis	L06
L07	L07	LH	Anergy Panel	L07
L08	L08	LI	PPD Skin Test	L08
L09	L09	LJ	Chlamydia Gen-Probe	L09
L10	L10	LK	Urinalysis	L10
L11	L11	LL	Urine Culture Result	L11
L12	L12	LM	(Urine) Pregnancy Test	L12
L13	L13	LN	Gonorrhea Gen-Probe	L13
L14	L14	LO	Colposcopy Results	L14
L15	L15	LP	Biopsy	L15
L15s1	L15	LP	Biopsy (A1: Biopsy results)	L15s1
L16	L16	LQ	Dysplasia Treatment	L16
L17	L17	LR	HSV Culture of Ulcers and Fissures	L17
L18	L18	LS	Trichomonas Vaginalis Culture	L18
L19	L19	LT	CVL Processing	L19
L20	N/A	LU	Repository Specimen Processing	L20
M01	M01	RH	CMV-GI Tract	M01
M03	M03	RI	CMV Radiculomyelopathy	M03
M04	M04	RJ	CMV Retinitis	M04
M05	M05	RK	Coccidioidomycosis	M05
M06	M06	RL	Cryptococcosis	M06
M07	M07	RM	Diarrhea/Gastroenteritis	M07
M08	M08	RN	Esophageal Candidiasis	M08
M09	M09	RO	Herpes Simplex Virus (HSV) AIDS Defining	M09
M10	M10	RP	Histoplasmosis	M10
M11	M11	RQ	Kaposi's Sarcoma	M11
M12	M12	RR	Encephalitis/Dementia/Non-TB & Non Crypt	M12
M13	M13	RS	Pneumonia	M13
M14	M14	RT	Progressive Multifocal Leukoenceph	M14
M15	M15	RU	Toxoplasmosis	M15
M16	M16	RV	Wasting Syndrome	M16
M17	M17	RW	Pelvic Inflammatory Disease	M17
M18	M18	RX	Oral Candidiasis	M18
M19	M19	RY	Candida Vaginitis	M19
M20	M20	RZ	Varicella Zoster	M20
M21	M21	DA	Death Certificate Abstraction	M21
MED1	MED1	AT	B/L Abstract Tracking Checklist	MED1
MED1p1	MED1	AT	B/L Abstract Tracking Checklist	MED1p1
MED2	MED2	AU	F/up Abstract Tracking Checklist	MED2

WDMAC Form	NERI Form	Tag	Description	Table
MED2p1	MED2	AU	F/up Abstract Tracking Checklist	MED2p1
MEN01	N/A	MP	Menopause Symtpoms	MEN01
MENS	MENS	MC	Menstrual Calendar	MENS
MENT	MENT	MA	Mental Alternations Test	MENT
MINOTI	N/A	MM	Mucosal Immunity Substudy Participant Notification	MINOTI
MSNOTI	N/A	MN	MS: Participant notification	MSNOTI
MS01	N/A	MS	MS: Specimen Collection for Metabolic Study	MS01
MS01s1	N/A	MS	MS: Specimen Collection (A7: ARV use)	MS01s1
MS01s2	N/A	MS	MS: Specimen Collection (A10: Date/time med taken)	MS01s2
MS02	N/A	ML	MS: Lab test report form	MS02
MS03	N/A	MX	MS: DXA scan form	MS03
MSKNOTI	N/A	MK	MSK: Participant Notification	MSKNOTI
MSK01	N/A	MG	MSK: Participant Data Log DXA/VFA	MSK01
MSK02	N/A	MQ	MSK: Participant Data Log QCT	MSK02
MVIS	MVIS	MV	Missed Visit Form/Report	MVIS
NACS	NACS	UF	NIDA Abstract Control Sheet	NACS
NC01A	N/A	NA	Cognitive Measures (Std TMT & SDMT) (NC Substudy)	NC01A
NC01B	N/A	NB	Cognitive Measures (Color TMT) (NC Substudy)	NC01B
NC02A	N/A	NC	English Word List (NC Substudy)	NC02A
NC02B	N/A	ND	Spanish Word List (NC Substudy)	NC02B
NC03	N/A	NE	Educational Experience (NC Substudy)	NC03
NC04	N/A	NW	Pronunciation Word List (NC Substudy)	NC04
NC05	N/A	NF	Interview Feedback (NC Substudy)	NC05
NC06	N/A	NG	Hopkins Verbal Learning Test	NC06
NC07	N/A	NH	Stroop	NC07
NC08	N/A	NI	Verbal Fluency	NC08
NC09	N/A	NJ	Letter Number Span	NC09
NC10	N/A	NK	Grooved Pegboard	NC10
NI01	NI01	UA	NIDA Sub-Study Interview	NI01
NI01p1	NI01	UA	NIDA Sub-Study Interview (H: HIV Beliefs)	NI01p1
NI02	NI02	UB	General Abstraction (Sect. A, B, C)	NI02
NI02p1	NI02	UB	General Abstraction (Sect. D, E, F)	NI02p1
NI02s1	NI02	UB	General Abstraction (E5: Narcotic Use)	NI02s1
NI02s2	NI02	UB	General Abstraction (C16-C29: ARV Use)	NI02s2
NI03	NI03	UC	Pneumonia Abstraction	NI03
NI04	NI04	UD	Pneumonia Episode	NI04
NI04s1	NI04	UD	Pneumonia Episode (B10: Pathogens)	NI04s1
NI04s2	NI04	UD	Pneumonia Episode (B16: Treatments)	NI04s2
NI05	NI05	UE	Diarrhea Abstraction	NI05
NI05s1	NI05	UE	Diarrhea Abstraction (B10: Pathogens)	NI05s1
NOTI	NOTI	OR	Oral Participant Notification	NOTI
NP01	N/A	NP	Baseline Neuropathy Signs and Symptoms	NP01
NP02	N/A	NQ	Follow-up Neuropathy Signs and Symptoms	NP02
NV01	NV01	IA	NIDA I/V Enrollment Interview	NV01
NV02	NV02	IB	Antiretroviral Drug Use	NV02
NV03	NV03	IC	NIDA Specimen Collection Form	NV03

WDMAC Form	NERI Form	Tag	Description	Table
NV04	NV04	ID	NIDA Specimen Processing Form	NV04
NV05	NV05	IE	NIDA Flow Cytometry Form	NV05
NV06	NV06	IF	NIDA RNA Quantification on CVL	NV06
NV07	NV07	IG	Urine Toxicology Form	NV07
NVNOTI	NVNOTI	IH	NIDA I/V Participant Notification	NVNOTI
OP01	OP01	OA	Medical Evaluation	OP01
OP02	OP02	OS	Research Interview	OP02
OP03	OP03	OC	Saliva Sample Collection	OP03
OP04	OP04	OD	Oral Mucosal Tissue Exam	OP04
OP04s1	OP04a	OD	Oral Mucosal Tissue Exam: Addendum (Lesions)	OP04s1
OP05	OP05	OF	Smear Results	OP05
OP06	OP06	OG	Tooth Count & Random Half Mouth	OP06
OP07	OP07	OH	Plaque Index	OP07
OP08	OP08	OI	Gingival Banding Score	OP08
OP09	OP09	OJ	Papillary Assessment	OP09
OP10	OP10	OK	Subgingival Plaque	OP10
OP11	OP11	OL	Coronal Caries	OP11
OP12	OP12	OM	Root Caries	OP12
OP13	OP13	ON	Gingival Bleeding	OP13
OP14	OP14	OO	Loss of Attachment	OP14
OP14p1	OP14	OO	Loss of Attachment	OP14p1
OP15	OP15	OP	Dental Prostheses	OP15
OP16	OP16	OQ	Oral Referral and F/U	OP16
PAQ	N/A	PQ	Physical Activity Questionnaire	PAQ
PBM	N/A	PB	Performance-Based Measurements	PBM
PK01	N/A	--	Eligibility for Intensive PK Substudy	N/A
PKNOTI	N/A	PN	PK: Participant notification	PKNOTI
PK02	N/A	PM	PK: Current Antiretroviral medication use	PK02
PK02s1	N/A	PM	PK: Current Antiretroviral medication use (B2: ARV Use)	PK02s1
PK02a	N/A	PA	PK: Antiretroviral adherence	PK02a
PK03	N/A	PH	PK: Recent illnesses, concurrent meds & OB/GYN hist	PK03
PK04	N/A	PU	PK: Recent substance use	PK04
PK05a	N/A	PW	PK: Weight and Specimen collection: group A	PK05a
PK05b	N/A	PV	PK: Weight and Specimen collection: group B	PK05b
PK05c	N/A	PT	PK: Weight and Specimen collection: group C	PK05c
PK06	N/A	PD	PK: Dosing of antiretroviral medications	PK06
PK06s1	N/A	PD	PK: Dosing of antiretroviral medications (A6: ARV Use)	PK06s1
PK08	N/A	PF	PK: Dietary Assessment	PK08
PQBL	N/A	PX	Baseline Pulmonary Questionnaire	PQBL
PQ02	N/A	PX	Follow-up Pulmonary Questionnaire	PQ02
PREP	N/A	BP	HIV Prevention Technologies	PREP
PRNOTI	N/A	PR	Pregnancy Protocol Enrollment Form	PRNOTI
PR01	N/A	P1	Pregnancy Form	PR01
PR02	N/A	P2	Postpartum Form	PR02
PR02s1	N/A	P2	Postpartum Form (A8: Pregnancy Outcome)	PR02s1
PTSD	N/A	PZ	Stress Assessment Questionnaire	PTSD

WDMAC Form	NERI Form	Tag	Description	Table
QCCD	N/A	CR	Quality Control Sheet for Review of Cancer Diagnoses	QCCD
QCCV01	N/A	UQ	Quality Control Carotid Ultrasound Tracking Form	QCCV01
QCGY	N/A	GM	Quality Control Sheet for Review of Gynecologic Material	QCGY
QCHS	N/A	HA	Hysterectomy Abstraction Form	QCHS
QCLB	N/A	LX	Liver Biopsy Abstraction Form	QCLB
QCSS	N/A	SS	QCSheet for Central Review of Surgical Specimens	QCSS
RAB	N/A	MR	Retrospective MRA (2001/02 & 2011/12 Recruits)	RAB
RABs1	N/A	MR	Retrospective MRA (B.5: 1st HAART regimen)	RABs1
RABs2	N/A	MR	Retrospective MRA (C.1.1.a: prior HAART regimen)	RABs2
RABs3	N/A	MR	Retrospective MRA (C.2.2.a: 2nd HAART regimen)	RABs3
RABs4	N/A	MR	Retrospective MRA (C.4.A.i: post HAART HIV RNA)	RABs4
RABs5	N/A	MR	Retrospective MRA (C.4.B.i: post HAART CD4)	RABs5
RABs6	N/A	MR	Retrospective MRA (B.3: pregnancy HAART regimen)	RABs6
RABs7	N/A	MR	Retrospective MRA (B.4: PEP/PrEP regimen)	RABs7
RACE	N/A	ER	Ethnicity and Race Questionnaire	RACE
SCR	N/A	ES	Screening Form (2001/02 & 2011/12 Recruits)	SCR
SCRs1	N/A	ES	Screening Form (C2: ARV Use)	SCRs1
SSNOTI	N/A	SN	SS: Participant notification	SSNOTI
SS01	N/A	SL	SS: Sex steroid lab test report form	SS01
TB	N/A	TB	Tuberculosis – Verified Case Report	TB
TRANS	TRAN	TR	Transfer Form	TRANS
VAC	N/A	VC	Vaccination History Form	VAC
VACs1	N/A	VC	Vaccination Hx (B1: Vaccination information)	VACs1
VNOTI	N/A	VN	VRS Enrollment Form	VNOTI
VRS03	N/A	VI	VRS Recent Illnesses and Medications	VRS03
VRS04	N/A	VA	VRS Antiviral Medications	VRS04
VRS05	N/A	VH	VRS Changes in HAART Regimen	VRS05
VRS06	N/A	VT	VRS Telephone Interview for Medical Providers	VRS06
VRS06s1	N/A	VT	VRS Telephone Interview (B2: ARV Use)	VRS06s1
VRS06r	N/A	VR	VRS Telephone Interview (2001/02 Recruits)	VRS06R
VRS06rs1	N/A	VR	VRS Telephone Interview (B2: ARV Use)	VRS06Rs1
VRS29	N/A	VB	VRS Blood Specimen Collection Form	VRS29

F. OFFLINE EDITING

On a semi-annual basis, WDMAC will generate site-specific batch edits and distribute these edits to the respective sites. The same edit procedure will be followed every six months so that a clean historical data set can be generated and distributed to the sites on a semi-annual basis.

Below is a description of the data that will be edited, the types of edits that will be generated and the procedures sites should follow to respond to these edits.

1. DATA TO BE EDITED

   All data that has been entered in a given visit's calendar time period may be subject to this semi-annual edit process.

2. TYPES OF EDITS

The types of edits generated in this process may include:

a. Range checks

A range edit indicates that a value has been entered for a variable that is out of the valid range defined for that particular variable.

b. Skip pattern checks

This type of edit is generated either when (1) a value has been entered into a field that other data have indicated should have been skipped due to a defined skip pattern, or (2) a field has been skipped that should have had a value entered.

c. Internal Consistency Check (ICC)

These checks generate edits when there are inconsistent answers for a participant internal to one form. An example of this would be data that indicate a participant has taken antiretroviral drugs since her last study visit but there is no record of any specific or "other" antiretroviral drug listed on the form.

d. Cross Form Check (CFC)

CFCs look for consistency between different sections of some of the longer forms (e.g., ***F22HX***), between forms and subforms (e.g., ***F08*** and ***F08s1***) and between different forms containing related data (e.g., ***F22MED*** and ***DRUG1***). In addition, they include edits of the DATEBASE summary file to check for visit date consistency across forms and visits. An example of this type of CFC would be if the visit date on Form ***F21*** is listed as 10/10/98, but the visit date on Form ***F22HX*** for that same visit is listed as 10/10/99.

f. LABSUM edits

These edits identify participants with a CD4 measurement but no viral load measurement for a particular visit number.

g. Pregnancy edits

These edits check longitudinal self-reported pregnancy data – i.e., if a pregnancy is reported at one visit, an edit will be generated if no outcome is reported at the next visit.

Range, ICC and skip pattern edits are sorted by visit number, then by WIHSID, and finally by table or dataset (corresponding to one of the WIHS forms). All other edits are sorted by form and WIHSID. The basic information listed for each edit is as follows: the type of edit generated (duplicate, range, skip, ICC or CFC), the exact question number on the form to which the edit pertains, a brief description of the problem, the WDMAC variable name for which the edit was generated and the value that is in the database for this particular variable. Range edits will also include the valid ranges as they are defined at WDMAC. Skip edits will include all variables included in the skip pattern and the values listed for each respective variable.

3. PROCEDURES FOR RESOLVING EDITS

Edits generated offline and distributed to the sites on paper will be resolved using the online Apollo edits system – modifications to existing values can be accomplished through the "View Data" or "Modify Data" options on the Apollo data menu and confirmation of existing values can be accomplished using the "Confirm Edits" option on the data menu.

G. DISTRIBUTION OF HISTORICAL DATA

After edits (first and, if necessary, second batches) have been resolved by the sites and the corrected data entered into Apollo, a clean or "frozen" historical database in MS Access and ASCII formats will be distributed to the sites on CD. These clean historical data are the data that investigators should use for the purpose of scientific analyses. Data in the online Apollo system should not be used for scientific purposes. Following is an approximate timeline for WIHS IV and V distribution of edits and historical data:

VISIT DATA	WDMS Version Distributed	Data to WDMAC	1st Round Edits from WDMAC	1st Round Edits Returned	2nd Round Edits from WDMAC	2nd Round Edits returned	Data Distributed
VISIT 31 (10/1/09–3/31/10)	v31	6/1/2010	6/18/2010	7/8/2010	7/23/2010	8/4/2010	8/25/2010
VISIT 32 (4/1/10–9/30/10)	v32	12/1/2010	12/20/2010	1/7/2011	1/24/2011	2/3/2011	2/24/2011
VISIT 33 (10/1/10–3/31/11)	v33	6/1/2011	6/20/2011	7/8/2011	7/25/2011	8/4/2011	8/25/2011
VISIT 34 (4/1/11–9/30/11)	v34	12/1/2011	12/20/2011	1/9/2012	1/24/2012	2/3/2012	2/24/2012
VISIT 35 (10/1/11–3/31/12)	v35	6/1/2012	6/20/2012	7/10/2012	7/25/2012	8/6/2012	8/27/2012
VISIT 36 (4/1/12–9/30/12)	v36	12/3/2012	12/20/2012	1/9/2013	1/24/2013	2/5/2013	2/26/2013
VISIT 37 (10/1/12-3/31/13)	v37	6/3/2013	6/20/2013	7/11/2013	7/25/2013	8/8/2013	8/29/2013
VISIT 38 (4/1/13-9/30/13)	v38	12/2/2013	12/19/2013	1/9/2014	1/23/2014	2/6/2014	2/27/2014
VISIT 39 (10/1/13-3/31/14)	v39	6/2/2014	6/19/2014	7/10/2014	7/24/2014	8/7/2014	8/28/2014
VISIT 40 (4/1/14-9/30/14)	v40	12/1/2014	12/18/2014	1/8/2015	1/22/2015	2/5/2015	2/26/2015
VISIT 41 (10/1/14-3/31/15)	v41	6/1/2015	6/18/2015	7/9/2015	7/23/2015	8/6/2015	8/27/2015
VISIT 42 (4/1/15-9/30/15)	v42	12/1/2015	12/18/2015	1/8/2016	1/22/2016	2/5/2016	2/26/2016
VISIT 43 (10/1/15-3/31/16)	v43	6/1/2016	6/20/2016	7/11/2016	7/25/2016	8/8/2016	8/29/2016
VISIT 44 (4/1/16-9/30/16)	v44	12/1/2016	12/20/2016	1/10/2017	1/24/2017	2/7/2017	2/28/2017
VISIT 45 (10/1/16-3/31/17)	v45	6/1/2017	6/20/2017	7/11/2017	7/25/2017	8/8/2017	8/29/2017
VISIT 46 (4/1/17-9/30/17)	v46	12/1/2017	12/20/2017	1/10/2018	1/24/2018	2/7/2018	2/28/2018

Appendix A: Variable Map of WIHS Medication Data

ANTIRETROVIRAL THERAPY MEDICATIONS

Form	Variable	Question	Description
DRUG1	DRUGD1	A.0	Antiviral drug code
F22	D101MH	F.2.B.1	OLD: Antiviral drug 1
F22	D102MH	F.2.B.2	OLD: Antiviral drug 2
F22	D103MH	F.2.B.3	OLD: Antiviral drug 3
F22	D104MH	F.2.B.4	OLD: Antiviral drug 4
F22	D105MH	F.2.B.5	OLD: Antiviral drug 5
F22	D106MH	F.2.B.6	OLD: Antiviral drug 6
F22	D107MH	F.2.B.7	OLD: Antiviral drug 7
F22	D108MH	F.2.B.8	OLD: Antiviral drug 8
F22	D109MH	F.2.B.9	OLD: Antiviral drug 9
F22	D110MH	F.2.B.10	OLD: Antiviral drug 10
F22MEDS3	DRG1MH	B.2.A	Antiviral drug code
F22RS1	DRUGDR	3	Antiviral drug code
F22S3	DRG1MH	F.2.A	Antiviral drug code
F29AS1	DCODBI	1.A	Antiviral drug code
F29AS2	DCDEBI	2.A.i	Antiviral drug code
MS01S1	DCODMS	A.7	Antiviral drug code
PK02S1	DCODPM	B.2	Antiretroviral drug code
PK06S1	DCODPD	OldA.6.a	Old: Antiretroviral drug code
RABS1	H1DCMR	B.3.1.b	Drug code - 1st HAART regimen
RABS2	ARDCMR	C.1.1.b	Drug code in ART regimen
RABS3	D2DCMR	C.2.2.c	Drug code in additional
SCR	PI1_ES	C.2	Drug code for PI which was
SCR	NNR1ES	C.3	Drug code for NNRTI which was
SCR	NR1_ES	C.4	Drug code for NRTI which was
SCRS1	DRUGES	C.2	Antiviral drug code
VRS04	DRUGVA	B.	Antiviral drug code

HEPATITIS B/C MEDICATIONS

Form	Variable	Question	Description
DRUG3	DRUGD3	A.0	Hepatitis drug code
F22MEDS9	DRGHMH	D.1	Hepatitis drug code

NON-ART MEDICATIONS

Form	Variable	Question	Description
DRUG2	DRUGD2	A.0	OI drug code
F22	D201MH	F.9.B	OLD: OI drug code 1
F22	D202MH	F.9.B	OLD: OI drug code 2
F22	D203MH	F.9.B	OLD: OI drug code 3
F22	D204MH	F.9.B	OLD: OI drug code 4
F22	D205MH	F.9.B	OLD: OI drug code 5
F22	D206MH	F.9.B	OLD: OI drug code 6
F22	D207MH	F.9.B	OLD: OI drug code 7
F22	D208MH	F.9.B	OLD: OI drug code 8
F22	D209MH	F.9.B	OLD: OI drug code 9
F22	D210MH	F.9.B	OLD: OI drug code 10
F22MEDS4	DRG2MH	C.1	OI drug code
F22S4	DRG2MH	F.9	OLD: OI drug code