

# WIHS Data Collection Forms

Where to Find What  
in the WIHS Database

Updated 4/5/2013

# Categories of Forms

- Baseline and follow-up core interview
- Physical and gynecological exams
- Specimen collection
- Local laboratory results
- Central laboratory results
- Reposited specimens
- Substudies
- Administrative
- Outcomes Ascertainment
- Miscellaneous Substudy Forms

# Core Interview

- Screening
  - *Foo* (1994/95)
  - *EL, SCR* (2001/02, 2011/12 & WIHS-V)
- 1994/95 recruit baseline
  - *F01-F06*
- 2001/02 recruit baseline
  - *F20, F20a, F22r, RAB, + F/up forms*
- 2011/12 & WIHS-V recruit baseline
  - *F20, F26r, RAB, RACE, + F/up forms*
- Follow-up
  - *F21-F26*

## Screening 1994/95 Recruits\*

- *Foo*
  - Race, ethnicity\*\*
  - Educational level – participant and mother \*\*
  - IDU – ever, last year of use\*\*
  - Sexual behavior – since 1980\*\*
  - Blood transfusions – 1975-1985\*\*
  - Self-reported HIV status

\* See MOO section 5, \*\* SOCDEM

## Screening 2001/02, 2011/12 & WIHS-V Recruits\*

- *SCR* (only selected variables data entered)
  - HIV status and testing dates
  - Prior HIV medication use
  - AIDS-defining illness (2011/12 & WIHS-V only)
- *EL*
  - Preferred interview language (2011/12 & WIHS-V only)
  - Race, ethnicity
  - IDU – past year
  - Sexual behavior – past year
  - Eligibility
  - DOB

\* See *MOO section 6*

## Baseline 2001/02, 2011/12 & WIHS-V Recruits\*

- *F20, F20a* (2001/02 only)
  - Medical history – ever
    - Cancer, HTN, diabetes, depression, HCV, CD<sub>4</sub><200
  - Ob/gyn, contraceptive history – ever
    - Pregnancy outcome\*\*, gyn surgery\*\*, oral contraceptive use, Pap history, STD history, mammography
  - Alcohol, drug use, sexual behavior – ever
    - Cigarette use\*\*\*, alcohol/drug treatment, drug use history\*\*\*, IDU\*\*\*, sexual risk factors\*\*\*, sexual identification\*\*\*
  - Educational level – participant and mother \*\*\*
  - Bilingualism – WIHS-V recruits only

\* See MOO section 6, \*\* OBGYN, \*\*\* SOCDEM

## Baseline 2001/02, 2011/12 & WIHS-V Recruits

- ARV use history (*F22r* for 2001/02 recruits only)
- Retrospective medical record abstraction (*RAB*)
  - Date first HAART use\*
  - ART use prior to HAART
  - Viral load, T-cells prior to HAART initiation
  - Viral load, T-cells post-HAART initiation

\* *HIVHIST*

## Sociodemographics (*F01, F21*)\* (1)

- Marital status\*\*
- Place of residence\*\*
- Household composition
- Employment status\*\*
- Income\*\*

\* See MOO sections 5 (BL) and 7 (FU), \*\* SOCDEM

## Sociodemographics (*F01, F21*)\* (2)

- Incarceration history
- Burden/support continuum
  - Adults in household
  - Childcare
- Parenting/parenting self-efficacy continuum
- Employment continuum
- Bilingualism (v35/36)

\* See MOO sections 5 (BL) and 7 (FU), \*\* SOCDEM

## Medical History (*F02, F22, F22HX*)\*

- HIV-related symptoms
  - Lipodystrophy
- Medical conditions, concomitant illnesses and symptoms
  - Cancer\*\*, TB\*\*, HTN\*\*\*, diabetes\*\*\*, hypercholesterolemia, depression, bone fractures, liver disease and HCV, heart conditions\*\*, serious head injury
- Skin and oral conditions
- AIDS-defining illnesses\*\*
- Biopsies
- Hospitalizations

\* See MOO sections 5 and 7, \*\* OUTCOME, \*\*\* RISKSUM

## Family and Personal Medical History (*HX*)

- Periodic administration
  - Visits 15/16 and 33/34 for 1994/95 recruits
  - Visits 15/16 (baseline) and 33/34 for 2001/02 recruits
  - Baseline for 2011/12 & WHS-V recruits
- Family history
  - Cancer, HTN, stroke, heart disease, diabetes, kidney disease, dialysis, osteoporosis, blood clots
- Personal history
  - Menarche, heart disease, liver conditions, blood clots, liver biopsy
- Hormone replacement therapy history

## Medication History (*F02, F22, F22MED*)\*

- Antiretroviral use\*\*
  - Reason for starting/stopping therapy
  - Structured treatment interruptions, adherence, compliance
- PEP/PrEP use for HIV- (v34+)
- Opportunistic infection (OI) medication use\*\*
- Hepatitis B and C medication use
- Vaccination history
- Influenza symptoms and treatment
- Hormone replacement therapy use
- Other prescription medication use (specify)\*\*\*
- Alternative and complementary medication use
  - Vitamins, herbs, homeopathic, etc.
- Symptoms

\* See MOO sections 5 and 7, \*\* AIDS DRUG, \*\*\* OTHER MEDS

# Antiretroviral Dosage (*DSG*)\*

- ARV usage\*\*
  - Since last visit
  - Current (past 3 days)
- Number doses per day
- Number pills/ml per dose
- Drug formulation
  - Tablets, capsules, liquid
  - Strength
- Stop date

\* See MOO section 7, \*\* AIDS DRUG

# Drug Forms\*

- One completed for each medication reported
- *Drug Form 1* (antiretrovirals)\*\*
  - Reason for and duration of use
  - Adherence
- *Drug Form 2* (non-ART, Opportunistic Infections)\*\*
  - Reason for and duration of use
- *Drug Form 3* (HBV, HCV)
  - Duration of use and reason for discontinuation
  - Adherence

\* See MOO section 7, \*\* AIDS DRUG

## Gynecologic History (*F03, F23, F23a*)\*

- OB/GYN and contraceptive history (*F03, F23*)
  - Gynecologic surgery\*\*, pregnancy outcomes\*\*, menstrual history
  - Birth control\*\*: hormones, barrier methods, etc.
  - Gynecological infections\*\*
  - Mammography and breast conditions
- Fertility and infertility history (*F23a*)
  - Visit 14 only

\* See MOO sections 5 and 7, \*\* OBGYN

## Substance Use/Sexual History (*F04, F24, F24BEH*)\*

- Cigarette\*\*, cigar and alcohol use\*\*
  - Duration, frequency, treatment
- Drug use\*\*
  - Marijuana, illicit methadone, cocaine, heroin, etc.
  - IDU history\*\*
  - Treatment
- Sexual behavior – male and female partners\*\*
  - Frequency, number of partners, risk behavior
- Recent sexual encounters
  - For drugs, money or shelter

\* See MOO sections 5 and 7, \*\* SOCDEM

## Health Care Utilization (*F05, F05a, F25, F25a, F25b*)\*

- Utilization of services (*F05, F25*)
  - Medical, dental, social, mental health
- Health insurance coverage\*\* (*F05, F25*)
- Satisfaction with and attitudes towards health care (*F05a, F25a*)
- Complementary/alternative therapy use (*F05a, F25a*)
  - Acupuncturist, herbalist, etc.
  - Diet, exercise
- Mental health care utilization (*F25b*)
  - Visit 23/24 only
  - Medication use
  - Counseling

\* See MOO sections 5 and 7, \*\* SOCDEM

## Psychosocial Measures (*F06, F26, F26r*)\*

- MOS Quality of Life Scale\*\*
- CES-D Depression Scale\*\*
- Social support
- Children
  - Death of, health status
- Sexual abuse
- Domestic violence
- Physical violence
- History of abuse (*F26r*)
  - Baseline data for 2001/02, 2011/12 & WIHS-V recruits

\* See MOO sections 5 and 7, \*\* SOCDEM

# Examinations

- Neuropathy assessment (*NP01, NP02*)
- Physical exam (*F07, F7r*)
- Gynecological exam (*F08*)
- Potential CVL contaminants (*F08a*)

## Neuropathy Assessment (*NP01, NP02*)\*

- Symptoms
  - Pain, aching, burning
  - “Pins and needles”
  - Numbness
- Perception of vibration
- Deep tendon reflexes
  - Baseline – ankle only
  - Follow-up – knee and ankle

\* See *MOO section 9*

## Physical Exam (*F07, F7r*)\*

- Physical characteristics, body habitus
  - Weight\*\*, height\*\* (used to calculate BMI\*\*)
  - Visual assessment of lipodystrophy
  - Body measures (including waist and hip circumferences\*\*), skinfolds, Bioelectric Impedance Analysis (BIA)
- Skin exam
- Oral exam
- Breast exam
- Blood Pressure \*\*, pulse

\* See MOO section 9, \*\* RISKSUM

# Gynecological Exam (*Fo8, Fo8a*)\*

- Gynecological exam
  - Cervix, uterus, adnexae
- Lesions and abnormalities
- Exam site tests
  - Trichomonas, clue cells, increased WBCs, yeast, amine odor
- Clinical impression
  - Menopausal status
  - Infections, abnormalities
- Colposcopy indication
- Potential CVL contaminants (*Fo8a*)

\* See MOO section 9

# Specimen Collection\*

- Plasma and cell separation and freezing (*F10, L20*)
  - Processing dates/times
- Blood specimen collection (*F09, F29, F29r*)
  - Fasting status
  - Specimen types, tube volumes
- ART usage assessment (*F29a*)
  - Date/time ART last taken prior to phlebotomy
- Physical exam specimen collection (*F11, F31, F31r, L20*)
  - Pregnancy test; urine, hair and gynecologic specimens
- Hair collection (*F31a*)\*\*
  - Color, texture, treatment history

\* See MOO section 10, \*\*See MOO section 24

# Local Laboratory – “L” Forms\*

- HIV-1 Elisa and Western Blot (*Lo1*)\*\*
  - HIV-positive at baseline
  - HIV-negative only at follow-up
- Hepatitis – Serum Antibody (*Lo2*\*\*\*\*)
  - Baseline only; HBsAg, HBsAb, HBcAb, HCV Ab
- CBC/differential (*Lo3, Lo3a*)
  - HGB, HCT, MCV, platelet count, WBC, differential
- Flow cytometry (*Lo4*\*\*\*)
  - CD4, CD8, CD3
  - HIV-negative – baseline, all visits 1-10, even visits 10-34; baseline only beginning with visit 36

\* See MOO section 10, \*\* HIVHIST, \*\*\* LABSUM, \*\*\*\* RISKSUM

## “L” Forms (2)

- Liver/renal function (*Lo5*)
  - AST, ALT, Alk. Phos., albumin, BUN, creatinine (used to calculate eGFR\*\*), bilirubin, GGT, calcium, phosphate
  - Odd visits only through v13, then all visits
- Syphilis screening – serum antibody (*Lo6*)
  - 1994/95 recruits – baseline, v4, v6
  - 2001/02, 2011/12 & WIHS-V recruits – baseline
- Anergy (*Lo7*)
  - Baseline and odd visits, discontinued visit 12
- PPD (*Lo8*) – discontinued visit 18

\*\* *RISKSUM*

## “L” Forms (3)

- Chlamydia (*L09*) – baseline only
  - 1994/95, 2011/12 & WIHS-V – gen-probe
  - 2001/02 – LCR
- Urinalysis (*L10*)
  - Discontinued visit 8 for 1994/95 recruits
  - Not done on 2001/02 recruits
  - Baseline for 2011/12 & WIHS-V recruits
- Urine culture result (*L11*)
  - On positive urinalysis
  - Discontinued visit 8

## “L” Forms (4)

- Urine pregnancy test (*L12*)
  - Unless > 50yo, s/p hysterectomy or bilateral oophorectomy
- Gonorrhea (*L13*) – baseline only
  - 1994/95, 2011/12 & WHS-V – gen-probe
  - 2001/02 – LCR
- Colposcopy results (*L14*)
  - Indication, type performed, abnormal findings and lesions, biopsies taken, anal colposcopy
- Histopathology report (*L15*)
  - Biopsy type, results

## “L” Forms (5)

- Treatment form (*L16*)
  - Indication for treatment, follow-up plan, treatment modality
- Herpes culture – ulcers and fissures (*L17*)
  - Oral and vaginal
  - Baseline only
- Trichomonas vaginitis culture (optional) (*L18*)
- CVL processing (*L19, L20*)

## Central Laboratory – “C” Forms\*

- Toxoplasma serology (C30) – baseline only, 1994/95
- HTLV I and II (C31) – baseline only, 1994/95
- Bacterial vaginosis gram stain (C45)
  - Collected every visit, tested through visit 12
- Chlamydia urine confirmatory test (C50)
  - Baseline, odd visits through visit 7 (1994/95), visit 16 (2001/02)
- LCR chlamydia confirmatory (C51)
  - Swabs, collected through visit 3

\* See MOO section 10

## "C" Forms (2)

- HPV by PCR from CVL (data to Strickler)
  - Collected every visit
- HPV by hybrid capture (data to Strickler)
  - PCR+ and sample of PCR-
  - Collected at every visit
- HIV-RNA quantification (electronic transmission to WDMAC)\*\*
  - HIV+ only
- Pap smear (C60)
  - Infections, abnormalities
- Syphilis (C65) – ulcers and fissures
  - Discontinued at visit 30
- HSV serum antibody (C66) – baseline only, 1994/95

\*\* LABSUM

# Reposited Specimens

- USC
  - DNA
- Fisher Bioservices
  - Immortalized B-cells
  - Bacterial Vaginosis (BV) slides
- Precision Bioservices
  - Plasma
  - Serum
  - Cells
  - Cervical Vaginal Lavage (CVL)
  - Urine – pellets and supernatant
  - Saliva

## WIHS Substudies (1)\*

- Oral Substudy (*MOO Section 13*)
- NIDA Health Care Utilization (*MOO Section 14*)
- NIDA Immunology/Virology (*MOO Section 15*)
- HHV-8 Substudy (*MOO Section 16*)
- Pregnancy Protocol (*MOO Section 18*)
- Viral Resistance Substudy (VRS) (*MOO Section 21*)
- Anal Substudy (*MOO Section 22*)
- Metabolic Toxicities Substudy (*MOO Section 23*)
- **Hair Collection Protocol (*MOO Section 24*)\*\***

\*See individual presentations under "Substudies" heading.

\*\* Active protocol.

## WIHS Substudies (2)\*

- Metabolic Substudy (MOO Section 25)
- Intensive Pharmacokinetics (PK) Substudy (MOO Section 26)
- Sex Steroid Substudy (MOO Section 27)
- Cardiovascular Substudy (MOO Section 30)
- **Neurocognition and Aging (MOO Sections 32, 33)\*\***
- **Musculoskeletal Substudy (MOO Section 37)\*\***
- Substudy enrollment tracking\*\*\*

*\*See individual presentations under "Substudies" heading.*

*\*\* Active protocol*

*\*\*\* WIHSIDS*

# Oral Substudy\*

- Study of the prevalence and prognostic significance of oral lesions; fungal and viral lesions; periodontal disease; saliva. Assessment of coronal and root surfaces; functional status; psychosocial and functional morbidity caused by oral lesions.
  - Discontinued after visit 20
  - Participants enrolled in Bronx, Los Angeles, San Francisco and Chicago
- Enrollment notification (*OPNOTI*)
- Medical Evaluation (*OP01*)
- Research Interview (*OP02*)
  - Oral health and hygiene
  - Dental care utilization
  - OHIP-14

\* See MOO section 13

## Oral (2)

- Oral exams and specimen collection (*OP03-OP15*)\*
  - Saliva sample; mucosal tissue exam, lesions; HSV results; tooth count; plaque index; gingival banding score; papillary assessment score; subgingival plaque sample collection; coronal caries; root caries; gingival bleeding score; loss of attachment; dental prostheses
- Oral Referral and Follow-up (*OP16*)
- Laboratory results
  - Stimulated saliva (*C70*)
  - Subgingival plaque (*C71*)
  - Erythematous candidiasis (*C72*)

\* *ORALSUM*

# NIDA Health Care Utilization\*

- Investigate the influence of drug use on utilization of health care services and medication regimen adherence.
  - WIHS/HERS collaborative
  - Participants with nadir CD<sub>4</sub><200
  - Visits 4-12
- Interview (*Nl01*)
  - Pain assessment
  - Pain medications
  - Medication, insurance, benefits
  - Beliefs about HIV / AIDS
- Abstraction (*Nl02, Nl03, Nl04, Nl05*)

\* See MOO section 14

## NIDA Immunology/Virology\*

- Influence of drug use on natural history of HIV-1 infection and disease progression.
  - Visits 7-14
  - Groups: no drug use; recent cocaine/heroin use; recent IDU
- Enrollment notification (*NVNOTI*)
- History of drug use (*NVo1*)
  - IDU, cocaine/opiate use, history of snorting drugs

\* See MOO section 15

## NIDA Immunology/Virology (2)

- Antiretroviral use (*NVo2*)
- Specimen Collection and Processing (*NVo3, NVo4*)
- Flow Cytometry (*NVo5*)
- CVL RNA quantification (*NVo6*)
- Urine Toxicology (*NVo7*)
  - Cocaine, opiates, creatinine

## HHV-8\*

- Determine clinical manifestations of HHV-8 infection; rate of HHV-8 shedding and factors associated with HHV-8 shedding in saliva and cervico-vaginal secretions.
  - Visits 10-12 (1994/95 recruits); baseline (2001/02 recruits)
  - Bronx, Los Angeles, San Francisco, Chicago
  - Forms entered by San Francisco site into ACCESS database; *HVNOTI* and *HVDENR* also entered into Apollo for tracking purposes

\* See MOO section 16

## HHV-8 (2)

- Administrative forms
  - Recruitment Outcome (*HVNOTI*), Missed Visit (*HVMVIS*), Disenrollment (*HVDENR*), Specimen Collection (*HVSPEC*)
- Lifetime experience with anal/oral sex – *F24*, visit 9 only
- Specimen collection
  - Whole stimulated saliva
  - Phlebotomy – San Francisco site only
  - Anal sampling at v10 (1994/95); baseline (2001/02)

# Pregnancy\*

- Investigate the influence of pregnancy on HIV+ women and how pregnancy alters the natural history of HIV disease. Data on ante-, intra- and postpartum complications and medications collected via clinician interview (through visit 20) and abstraction by OB designee.
  - Visits 10-22
- Enrollment notification (*PRNOTI*)

\*See MOO section 18

## Pregnancy (2)

- Pregnancy (*PR01*)
  - Gestation
  - Antepartum complications and medication use
- Post-partum (*PR02*)
  - Outcome
  - Intrapartum: complications, labor and delivery summary, labs, medications
  - Postpartum: history and complications, medications on discharge

# Viral Resistance and Rebound (VRS)\*

- Address the long-term epidemiology, clinical outcomes and virologic characteristics of antiretroviral treatment failure.
  - Prospective visits every 3 months, visits 13-19, to perform in-depth assessments of participants who have experienced immunological response to HAART.
  - Retrospective analysis to determine incidence and prevalence of viral rebound on HAART and relative frequency of viral rebound with wild type and PI-resistant viral strains.
  - Bronx, Brooklyn, DC, San Francisco and Chicago
- Enrollment notification (*VRSNOTI*)

\*See *MOO section 21*

## VRS (2)

- Recent illnesses and medications (*VRS03*)
  - Symptoms and infections
  - Vaccinations
  - Medication use – stomach, psych, prednisone, tamoxifen, antibiotics
- Antiretroviral medications (*VRS04*)
  - Current use, dosage, adherence
- Screening to determine changes in HAART regimen (*VRS05*)
- Telephone interview for medical providers (*VRS06*, *VRS06r*)
  - Documentation of ART regimen changes
- Plasma separation and screening (*VRS10*)
- Blood specimen collection (*VRS29*)

## Anal\*

- Study the natural history of anal HPV infection; development and progression of ASIL in the era of HAART. Compare the natural history and risk factors for anal HPV infection to those of cervical HPV infections. Analyze genetic changes in ASIL women.
  - Brooklyn, San Francisco, Chicago
  - Forms developed, data entered, analyzed by San Francisco
- Cervical cytology, colposcopy, cervical HPV data from WIHS core

\* See MOO section 22

# Metabolic Toxicities\*

- Cross-sectional assessment of metabolic abnormalities, fat redistribution, osteoporosis, osteopenia and protease inhibitor exposure. Determine bone density and fat distribution; menopausal status; fasting insulin, blood glucose and lipid profiles.
  - Bronx, San Francisco
  - Visit 13
  - Forms developed, data entered, analyzed by Bronx

\* See MOO section 23

# Hair Collection\*

- Investigation of adherence to antiretroviral medications by measuring drug levels in hair samples.
  - Collection began during visit 17
  - All participants who are HIV positive and have taken antiretroviral medication(s) within the four weeks prior to their core visit are eligible for participation in the hair collection protocol
  - Beginning with visit 34, all HIV-positive women, regardless of ARV medication use, are eligible for participation
- Hair Color, Texture and Treatment History Form (*F31a*)
  - Natural hair color
  - Percent gray hair
  - Natural texture of hair
  - Hair treatments (color, highlights, straightening)

\* See MOO section 24

# Metabolic\*

- Prospective assessment of metabolic complications in pre- vs post-menopausal women. Examine the effects of HIV infection, ART and family history of diabetes, hyperlipidemia or cardiovascular disease on glucose tolerance, diabetes, hyperlipidemia, fat redistribution and osteopenia/osteoporosis.
  - Visit schedule
    - Baseline: visits 18-21
    - Follow-up #1: visits 22-25
    - Follow-up #2: visits 29-31
  - Bronx, San Francisco and Chicago
  - In addition to DXA and OGTT, SF site only will perform MRI
  - All participants will have baseline lipid panel, and NMR lipoprofile

\* See MOO section 25

## Metabolic (2)

- Enrollment notification (*MSNOTI*)
- Specimen collection (*MS01*)
  - Medication assessment – diabetes, ART
  - OGTT specimen collection
- Lab test report form (*MS02*)
  - Glucose and insulin – fasting, 30, 60, 120 min
- DXA scan form (*MS03*)
  - Spine
  - Left hip
  - Whole body

# Intensive Pharmacokinetics\*

- Perform intensive pharmacokinetics sampling to determine bioavailability and clearance rates for six target antiretroviral medications. Model factors that contribute to inter-individual variability in overall treatment exposure.
  - Sustiva, Viramune, Viracept, Kaletra, Reyataz, Isentress
  - Protocol implemented at visit 18
  - Bronx, Brooklyn, DC, San Francisco and Chicago
- Enrollment notification (*PKNOTI*)
- Antiretroviral use and adherence (*PKO2, PKO2a*)
  - PKO2a – one completed per target drug reported

\* See MOO section 26

## Intensive PK (2)

- Recent illnesses (30 days), concurrent meds (5 days), ob/gyn history (*PK03*)
  - Stomach, seizure, heart and blood pressure, cholesterol, psych, prednisone, tamoxifen, antibiotics
- Recent substance use (*PK04*)
  - Cigarette and alcohol
  - Illicit drugs
- Weight and PK specimen collection (*PK05a, PK05b, PK05c*)
- Dosing of antiretroviral medications (*PK06*)
  - Number of pills, drug formulation
- Dietary fat percentage assessment (*PK08*)

# Sex Steroid\*

- Evaluate the effects of HIV infection on age of onset of diminished ovarian reserve, on peri-menopausal changes in menstrual cycle characteristics, and on the age at menopause.
  - Visits 18-24
  - Retrospective testing of all WHS participants began during visit 25 – separate enrollment into substudy is no longer required
- Participation notification and specimen collection (*SSNOTI*)
  - Verification of date of menstruation
- Lab test report form (*SS01*)
  - FSH, estradiol, inhibin B, DHEA, DHEA-S, SHBG
- MIS/AMH testing done retrospectively

\* See MOO section 27

# Cardiovascular\*

- Assessment of cardiovascular disease, including subclinical atherosclerosis, cardiovascular risk factors, carotid artery intima-media thickness (IMT), and clinical cardiovascular events.
- Visit schedule
  - Baseline: visits 20-22
  - Follow-up #1: visits 25-27 (subset of baseline participants)
  - Follow-up #2: visits 29-33 (subset of baseline participants)
  - Follow-up #3: visits 33-35 (subset of baseline participants)
- Enrollment notification (*CVNOTI*)
- Carotid ultrasound tracking form (*CV01*)\*\*
  - US type (BL, FU, QC); equipment used; lesions; BP
- Specimen collection (*CV29*\*\*\*)
  - Fasting specimens for lipid profile, insulin, NMR lipoprotein, glucose

\* See *MOO section 30*, \*\* *CVOUTCOME*, \*\*\* *LIPIDS*

# Neurocognition and Aging\*

- Interaction between aging and HIV/AIDS on neurocognitive functioning. Identify and characterize physical impairment, including frailty syndrome, mobility-based instrumental activities of daily living and physical functioning.
  - WIHS-III Neurocognitive assessment implemented at visit 21
  - Physical functioning assessment implemented at visit 22
  - WIHS-IV Neurocognitive assessment implemented at visit 30
- Standard Trail Making Task (TMT) and Symbol Digit Modalities Task (SDMT) (*NCo1a*) (visits 21-24; 30+)
  - TMT parts A and B
- Color Trail Making Task (*NCo1b*) (visits 21-22)
  - Los Angeles and DC sites only

\* See MOO sections 32 and 33

## Neurocognition and Aging (2)

- Wide Range Achievement Test – Version 3 (*NCo2a*) (visit 21, 22 or 30+)
  - One-time administration; English- & Spanish-speakers
  - Reading Recognition subtest measures English reading level
- WAT (*NCo2b*) (visit 21, 22, 23 or 30+)
  - One-time administration; Spanish-speakers only
  - Measures Spanish reading level
- Educational experience (*NCo3*) (visit 21, 22 or 30+)
  - One-time administration; English- & Spanish-speakers
  - Assessment of elementary, high school, post-high school education
  - Years completed, location, setting, ethnic composition

## Neurocognition and Aging (3)

- Wechsler Test of Adult Reading (WTAR) (*NCo4*) (visit 22, 23 or 30+)
  - One-time administration; English-speakers only
  - Assessment of premorbid intelligence
- Interviewer feedback (*NCo5*) (visits 21-24, 35+)
- Hopkins Verbal Learning Test (*NCo6*) (visits 25; 30+)
  - Immediate and delayed recall
- Stroop (*NCo7*) (visits 25; 30+)
  - Color naming
  - Word reading
  - Interference

# Neurocognition and Aging (4)

- Verbal Fluency (*NCo8*) (visits 30+)
  - Letter and semantic fluency
- Letter- number Span Task (*NCo9*) (visits 30+)
  - Experimental and control conditions
- Grooved Pegboard (*NC10*) (visits 30+)
  - Dominant and non-dominant hands
- Stress Assessment Questionnaires (*PTSD*) (visits 29+)
  - Civilian PTSD – PCL-C
  - Perceived Stress Scale-10
- Menopause Symptoms (*MENo1, BLSA*) (visits 25; 29+)
  - Selected BLSA survey questions on menstrual history
  - SWAN questionnaire – symptoms and sleep habits

# Neurocognition and Aging (5)

- Lawton Instrumental Activities of Daily Living (*IADL*) (visits 38+)
  - Long form at baseline (v38-41)
  - Short form at follow-up (v42+)
- Physical functioning assessment (visit 22)
  - Activities of daily living
- Physical Activity Questionnaire (*PAQ*) (visit 22)
  - Adapted from the Fat Redistribution and Metabolic Changes in HIV Study (FRAM)
- Performance based measurements (*PBM*) (visit 22)
  - 3- or 4-meter measured walk (timed gait)
  - Grip strength

# Musculoskeletal Substudy

- Assess effect of estrogen deficiency during menopause on bone strength and muscle and immune function.
  - BL at visits 35-39; F/up at visits 39-42
  - Approximately 330 women to be enrolled at Bronx, San Francisco and Chicago sites
  - Women must be 40-60 years old – either in late perimenopause or early postmenopause
- Enrollment Notification (*MSKNOTI*)

\* See MOO section 37

## Musculoskeletal Substudy (2)

- Physical Activity Questionnaire (*PAQ*)
- Functional Performance Tests (*PBM*)
  - Standing Balance Test
  - Functional Reach Test
  - Repeated Chair Stands
  - Grip Strength
  - 4-meter Walk
  - 400-meter Walk
- Phenotypic assessment of frailty

# Musculoskeletal Substudy (3)

- Sera and cells
  - Gonadal and calcitropic hormones
  - Cytokines (TNF $\alpha$ , IL6, RANKL, osteoprotegerin)
  - Bone turnover markers (osteocalcin, C-telopeptide)
- Dual X-ray Absorptiometry (DXA) (*MSK01*)
  - AP spine
  - Left hip
  - Forearm
  - Whole body
- Vertebral Fracture Analysis (VFA) (*MSK01*)
- Quantitative Computed Tomography (QCT) (*MSK02*)
  - Spine
  - Hip

# Administrative Forms

- Abbreviated visit (*ABRV*)
  - Completed (with *F22HX*, *F22MED\**, *DSG\**, and *DRUG1\**) when participant cannot attend a full visit
- Disenrollment (*DENR*)\*\*
  - Completed for participants who die or disenroll from WIHS core and/or substudies
- Interim events (*INT*)
  - 3-month interim telephone interview for participants with  $CD_4 < 200$
  - Assessment of AIDS status
  - Started v10; optional v17; discontinued v20

\* *AIDSDRUG*, \*\* *OUTCOME*

# Administrative Forms (2)

- Missed visit (*MVIS*)
  - Completed for participants who miss a core or oral substudy visit
- Transfer (*TRANS*)\*
  - Completed for participant transfers between sites and subsites
  - DOB
  - Preferred language
  - HIV status
  - Substudy enrollment
  - Visit dates
  - Assigns new WIHSID

\* *DATEBASE*

# Administrative Forms (3)

- Consent Tracking Form (*CONS*)
  - Indicator for each participant
  - Completed at baseline for all participants and follow-up visits (if status changes)
    - Genetics
    - B-cell
    - Commercial use of B-cells
    - GWAS
- Direct Data Entry Form (*DDE*)
  - Visits 38+
  - Indicator for each interview form: Was form administered on paper or via DDE?

# Outcomes Ascertainment\*

- Clinical outcomes reporting (*CORE*)\*\*
  - Ascertainment of AIDS-defining diagnoses, cancer, TB, heart disease, deaths
  - Date of diagnosis
  - Level of confidence in diagnosis
  - Supplemented with National Death Index information
  - USRDS – renal registry matching data (v35)
- Ascertainment Tracking Checklist (*ATC / ACSRATC*)\*
  - Events and biopsies needing ascertainment
  - Confirmation status

\* See MOO section 12, \*\* OUTCOME

## Outcomes Ascertainment (2)

- Cancer Registry Case Report (*CNCR*)\*
- TB – Verified Case Report (*TB*)\*
- QC Review of Gynecological Material (*QCGY*)
  - Cervical biopsy central review
- Central Review of Surgical Specimens (*QCSS*)
  - Other biopsy central review
- QC Review of Cancer Diagnoses (*QCCD*)
- Liver Biopsy Abstraction Form (*QCLB*)
- Hysterectomy Abstraction Form (*QCHS*)\*\*
- Vaccination Form (*VAC*)
  - Hepatitis A and B, HPV, pneumococcal, tetanus, influenza, others
  - Visits 25-29

\* *OUTCOME*, \*\* *OBGYN*

# Miscellaneous Substudy Forms (1)

- Pulmonary Questionnaire (Ro1-funded study)
  - Baseline (*PQBL*) – visit 27
  - Follow-up (*PQo1*) – visits 29 and 31
  - Symptoms, treatments and medication use, diagnoses
- Female Sexual Functioning Inventory (*FSFI*)
  - Visit 25, self-administered
  - Assessment of sexual arousal and activity
- HPV Knowledge and Beliefs (*HPVKAB*)
  - Visits 26, 29/30, and 33/34, self-administered
- Opinions about the Health System and HIV/AIDS (*TRUST*)
  - Visit 24, self-administered

## Miscellaneous Substudy Forms (2)

- Ethnicity and Race Questionnaire (*RACE*)
  - Visit 35/36; BL for 2011/12 & WIHS-V recruits
  - Collection of race/ethnicity data according to U.S. Census categories
- New Biomedical HIV Prevention Technologies (*PREP*)
  - Visit 35, HIV-negative participants only
  - Knowledge regarding PrEP and vaginal microbicides

## Miscellaneous Substudy Forms (3)

- Brief Pain Inventory Short Form (*BPI*)
  - Visit 37, all participants; WIHS-V, baseline
  - Experience with pain and pain medications over the last week of the participant's life
- Pain Medication Use Questionnaire (*PMU*)
  - Visit 37, all participants; WIHS-V baseline
  - History of medications the participant ever used, where the medications were obtained, and the frequency of use

## Miscellaneous Substudy Forms (4)

- Autoimmune Disease Form (*ADF/ADF02*)
  - Visits 37-40, all participants
  - Ever and SLV diagnosis of autoimmune diseases and medication treatment history
    - Lupus
    - Sjogren's syndrome
    - Multiple sclerosis
    - Graves disease
    - Hashimoto's thyroiditis

# Miscellaneous Substudy Forms (5)

- Food Insecurity Study (*FIS*)
  - Visits 38+, all participants
  - Food security and hunger (every 6 months)
  - Dietary quality (annual)
  - Socioeconomic data (annual)
  - Receipt of food assistance (annual)
  - Competing demands (annual)
  - HIV stigma (annual)

# Conclusions

- Let WDMAC do the work for you:
  - Whenever possible, use summary files
- To use data not included in summary files:
  - Review forms, codebooks, protocols
  - Forms, QxQs, codebooks, input files, data dictionary (index file), MOO are all online:  
<http://statepiaps.jhsph.edu/wihs/admin>
  - Available in raw files (*F07*, *F22HX*, etc.) on data DVD distributed to sites