Within Country Biomarker Issues

- Sample collection protocols – feasibility, pros/cons, other issues?
  - DBS vs. Venous
  - Point-of-Contact
  - Other non-blood
    - Lung Fx
    - BP
    - BMI/WHR
    - Performance – e.g., cognitive and physical Fx
Within Country Biomarker Issues (cont’d)

- Laboratories
  - Initiation evaluation (e.g., validation of assays)
  - On-going oversight - Quality control (over time)

- Sample storage (over time)

- Reporting issues – what information should/can be reported back to participants
  - Non-genetic
  - Genetic?
Harmonization Issues: Between Country Comparisons

- Equilibration between laboratories
  - NIH HIV centralized laboratory infrastructure for “clinical trials network”
  - Smaller scale options?
    - Centralized vs. decentralized?
    - Developing algorithms for cross-laboratory equilibration
      - Maintaining overtime?
Group Discussion

- Common & unique issues faced by various of the different international studies?
  - Build on morning study-specific information
    - “issues” they face relating to biomarker data collection

- Going forward - How best to address common “issues”
  - Infrastructure?
  - Other needs
Main Steps for Establishing New DBS-Based Assays

- *Training* of laboratory personnel
- Securing *equipment* for the assays
- Obtaining *test reagents and supplies*
- *Assay validation*: including pre-test with validation samples
- Ongoing *quality control* during testing of study samples
More Lessons Learned

- Need to conduct well-designed pre-test and ongoing monitoring to ensure data quality for DBS-based assays
- Good pre-test and quality control rely on availability of adequate validation samples, which requires infrastructure, expertise, and funding typically beyond what studies can do individually
- Maintain ongoing and timely communication with the laboratories that conduct DBS-based assays is crucial, but may be challenging
Major Questions Remain

- No current specific criteria defining *acceptable assay quality and between-laboratory variability*
  - How good is good enough (or how bad is not good enough)?

- In addition to good pre-test and quality control for each individual study, how can we compare DBS-based results across different surveys/countries?
  - Need for macro-level infrastructure
  - Laboratories for most surveys are operational for only a short period of time

- What are the other support/services USC/UCLA Biodemography Center may be able to provide?
Group Discussion

- Commonalities & unique issues faced by various of the different international studies?

- Future Priorities? How can we collaboratively move the field forward?
  - What needs to be developed?
  - What infrastructure would be optimal?
Future Directions
“next steps”/priorities

- Your Ideas?