NHANES Open Space
September 11-12, 2003

Session Title: Ancillary studies – DNA, serum, urine

Session Headlines:

1. Potential new, cutting edge lab tests to be added to HANES

Already discussed in an earlier session

Gene analysis – can be expensive

Genetic consent issues

Tests with direct clinical relevance – are they appropriate for stored specimens?

CRP – should we report results to participants?

Sponsors should consider doing immediate testing for items of clinical relevance rather than doing those tests on stored specimen. That way on time reporting becomes possible.

Linkage and disclosure issues

Ancillary test data, therefore, may not be made publicly available.
Survey data analysis centers may be useful in this context.

Secured data centers.

Data validity issues: asking major journals to include NHANES experts as reviewers for manuscripts using NHANES data.

Newsletters on ancillary study findings on stored specimens.

Access by researchers vs. private industry – how to set rules?

Clinical trial data release guidelines being developed by NIH – private industry sponsor will have access only when data are publicly released. And PIs should publicly release data within a set time period after completion of study (usually 1-3 years).

Analytic centers – often provide original program coded for published papers (for the purpose of duplication).

New technologies for specimen processing, storage and retrieval

Next Steps/Action Items:

Improve consent procedures for future research

Work with NIH and other agencies to increase analyses on surplus specimens

Be on the lookout for new methods and technologies

Make requests for proposals for analyses of future specimens. Proposals could use approximate sample sizes.

Charge overhead for funding for specimen storage, processing and analyses.

Charge for consultation expenses

Administrative help and creation of fellowships

Recruit a genetic epidemiologist