Biostat 513: **Discussion Section Data Analysis #1**

INTRODUCTION:

A substantial body of evidence suggests that the process of obtaining informed consent from participants in clinical research is often inadequate. Numerous reports have described research participants who neither were informed of nor consented to research participation, as well as participants who did not fully understand the nature and potential implications of research to which they were consented. Such reports have prompted calls for improvement of the informed consent process based on available information, as well as for additional research to guide further improvement.

Most studies of the informed consent process have focused on clinical trials of biomedical interventions and the potential risks of investigational products and required study procedures. Potential efficacy trials of preventive HIV vaccines present unique additional challenges for protection of human subjects. Potential issues include stigmatization/discrimination due to incorrect interpretation of standard HIV antibody tests, and/or an incorrect presumption that participants in HIV vaccine efficacy trials are infected with HIV. In addition, HIV vaccine trial participants may increase their HIV risk behaviors due to a belief in protection afforded by candidate HIV vaccines (placebo controlled trials). Given these unique additional challenges, the US Office for Technology Assessment (OTA) and others have proposed guidelines for obtaining informed consent in future vaccine efficacy trials. Others have called for the development and evaluation of methods to convey this information, and to document potential subjects' understanding of it, prior to implementation of large-scale trials.

To develop methods to assure that participants in future HIV vaccine trials understand the implications and potential risks of participating, the HIVNET developed a prototype informed consent process for a hypothetical future HIV vaccine efficacy trial. A 20% random subsample of the 4,892 Vaccine Preparedness Study (VPS) cohort was enrolled in a mock informed consent process at month 3 of the study (between the enrollment visit and the scheduled follow-up visit at month 6). Knowledge of 10 key HIV concepts and willingness to participate in future vaccine efficacy trials among these participants were compared with knowledge and willingness levels of participants not randomized to the informed consent procedure.

The data `hivnet.data` contains observations from the informed consent subset (IC group). We will analyze these data to answer the following questions:

- Does willingness to participate in vaccine trials at month 6 depend on the level of knowledge for the participant?
- Does willingness to participate in vaccine trials at month 6 depend on the *change* in knowledge (from baseline) for the participant?
- Is the relationship between willingness and knowledge constant across risk groups and educational attainment levels?
- (Challenge): Does *change* in willingness to participate in vaccine trials depend on the *change* in knowledge (from baseline) for the participant?

Analysis Variables:

`will6`	willingness at Month 6 (1=definitely willing)
`know6`	knowledge score for 10 key items at Month 6
`riskgroup`	risk group for enrollment
`education`	educational attainment
`cohort`	recruited from previous study or a new participant
`age`	age of participant in years
`q4safe6`	Question 4 = "sure that vaccine is safe" at Month 6
`will0`	willingness at baseline (1=definitely willing)
`know0`	knowledge score for 10 key items at baseline
`q4safe0`	Question 4 = "sure that vaccine is safe" at baseline

Week 1: April 17, 2002

1. Summarize the univariate distribution of each variable.
2. Summarize the bivariate relationship between willingness and knowledge (both `q4safe6` and the score).
3. Summarize the bivariate relationship between willingness and risk group, education, cohort, and age.
4. Summarize the bivariate relationship between knowledge and risk group, education, cohort, and age.
5. Classify the variables with respect to the primary question.
6. Formulate the scientific questions in terms of statistical hypotheses within a logistic regression.

Week 2: April 24, 2002

1. Use logistic regression to model the probability of willingness as a function of knowledge and other variables.
2. Use logistic regression to model test whether the willingness / knowledge relationship is different for levels of education and/or risk group.
3. Use logistic regression to evaluate the relationship between the change in the response to "is safe" from baseline to month 6 and the willingness to participate at month 6.

Week 3: May 1, 2002

1. Use logistic regression to evaluate the relationship between the change in the knowledge score from baseline to month 6 and the willingness to participate at month 6.
2. Assess the adequacy of the models used to answer the primary questions.
3. Conclusions?