Attachment 25: Report Prostate Pilot to NCI-IRB

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date March 27, 2006

From Stefan Ambs Ph.D., LHC, CCR, NCI

Subject Continuing Review of Protocol "A CASE-CONTROL STUDY OF PROSTATE CANCER IN THE GREATER BALTIMORE AREA"
a) Response to Changes in the Protocol
b) Progress Summary
c) Complaints/Breaches of Confidentiality

To Chair, Special Studies IRB

Attached please find the original and 20 copies of our continuing review application for protocol, 05-C-N021. We respectfully request that this protocol be reviewed during the April 2006 SSIRB meeting. The completed NIH-1195-1 form, the Precis of the protocol, recruitment tables, consent forms, and documentation of IRB approval at the participating institutions are attached.

The continuing review process requires that the principal investigator provides a response to all 'yes" answers on the NIH-1195-1 form, a summary of the protocol progress to date, and a report on complaints from participants or breaches of confidentiality. The latter is not further discussed in this report because we did not have complaints from participants or a breach of confidentiality.

There have been minor changes to the protocol since the last review of the protocol in May/June of 2005. In our first amendment, approved in July 2005, we requested changes to the eligibility criteria. We changed the age limit for participants from 80 to 90 years and expanded the recruitment of cases to self-identified African-American and Caucasian men who have been diagnosed with the disease within the last two years (instead of one year) prior recruitment. We also started recruiting cases that are living in Western Maryland, Washington DC, Virginia, West Virginia, and Pennsylvania. These changes have been made to increase case recruitment. In a second amendment, approved in December 2005, we requested changes to the questionnaires. These changes were made to both the main questionnaire and the supplemental questionnaire. The changes removed redundancies, clarified questions, shifted a section from the supplemental into the main

questionnaire and lead to the addition of a few new questions. Overall, the changes improved the quality of our survey.

Our protocol received approval by the NCI IRB on 10/28/2004. The protocol was not immediately implemented and the study started in February of 2005. The first year was designed to be a pilot with the following recruitment goals: Recruitment of 80 cases and population-based controls, respectively, and collection of 25 fresh-frozen prostate tumors. Cases and controls should consist equally of African-American and Caucasian men. We did not fully achieve our goals. As of March 27, 2006, we succeeded in recruiting 74 cases and 51 controls for the study. We also collected 12 fresh-frozen tumors. The distribution of the recruited cases and controls by race/ethnicity is shown in the table below.

	African-American	Caucasian	Total
Cases	39	33	72
Controls	20	31	51

The number of recruited cases is only 10% below recruitment goal and we were successful in recruiting African-American prostate cancer patients. We are confident that we will be able to recruit at least 80 cases per year in the future. We had very low recruitment numbers in the first 5 months of the study (a total of 8 cases only). We now have established an infrastructure to efficiently identify and recruit prostate cancer patients at the two participating hospitals and our monthly recruitment numbers have reached 10 cases per month and already 12 more cases are scheduled to be interviewed by the end of April 2006. We also added one more interviewer to the study, who will help with the recruitment of cases and controls. The below target number of recruited population-based controls is not the result of a problem to recruit eligible controls. Because of our study design to match recruited cases with controls in a batch procedure (frequency matching by age and race), the recruitment of controls will always lag

behind the recruitment of cases by 20-50. Initially, we had selected prospective population-based controls randomly from a DMV database. This control population was not matched to cases. After this initial recruitment effort, we focused on the recruitment of cases but will now resume the recruitment of controls. We are confident that we will be able to match all recruited cases with controls.

The participation rate among the eligible cases and controls has been very good. As of 3/27/2006, we have screened 457 prostate cases for eligibility. Of those 94 were eligible, 126 are currently evaluated, 67 had unknown eligibility and were not contacted, 2 could not be contacted, and 168 were ineligible. Of the 94 eligible, 72 participated, 12 have an interview scheduled, and only 10 refused (11%). Of the 168 ineligible cases, 106 were ineligible because of a diagnosis that was more than 2 years ago. However, this number of ineligible cases should decrease substantially with the continuation of the study because we should now be able to contact most cases shortly after the diagnosis of prostate cancer. The participation rate of male population-based controls that were eligible for the study has been 86%.

Another goal of the pilot was the collection of 25 fresh-frozen tumor samples from cases with an epidemiological profile. We could not achieve this goal and collected only 12 tumors. This is explained by the fact that neither the UMD Medical Center nor the Baltimore VA Hospital has currently a designated prostate surgeon on staff. There are only few surgeries performed at this time, and to our best knowledge all prospective surgery cases are reported to us. Thus, we are not missing cases. We have spoken to the director of the UMD Cancer Center, Dr. Cullen, about this problem and he assured us that the University is seeking to recruit a surgeon to specifically perform prostatectomies among prostate cancer cases. A selected candidate may start in summer of 2006. We are aware that the collection of fresh-frozen tumor samples will continue to lag behind our goal of 25 per year until a new prostate surgeon has been recruited.

In summary, we should be able to recruit at least 80 cases and the same number of controls per year over the next four-year period to reach the projected study size of 400 cases and 400 controls. The objective of our study is to identify genetic and environmental factors that predispose African-American males to a higher prostate cancer incidence and mortality than Caucasians. This is still an unexplored research field of high public interest. Thus, we believe that the continuation of the study is warranted and respectfully request that study continuation is approved.

Sincerely,

Stefan Ambs, Ph.D.

Attachments

- NIH-1195-1
- Precis
- Recruitment tables showing distribution by race/ethnicity
- Current consent forms
- Most recent IRB approval at participating institutions (UMD IRB is approving for both UMMS and VA)