

September 8, 2011

Clinical and Translational Research Operations Committee
Coordinating Center for Clinical Trials
National Cancer Institute
6120 Executive Blvd., Suite 300, MSC 7227
Rockville, MD 20852-7227

Dear Members of Committee:

We write to you as a coalition of organizations committed to improving treatment options for people with human papillomavirus (HPV)-associated malignancies. Today, we offer our support for the HOST-HGAIN Outcome Study to improve patient outcomes for people with anal precancer and cancer.

Anal cancer is a growing public health concern, especially as the aging HIV-positive and AIDS community increases. Across all populations, anal cancer is increasing for both men and women at a rate of about 2 percent a year. In 2011, the NCI estimates that there will be 5,820 new cases, a number significantly higher than the 2010 estimate of 5,260 new diagnoses. Men who have sex with men (MSM) are seventeen times more likely to develop anal cancer and HIV-positive MSM are fifty-eight times more likely to develop anal cancer than the general population. Although the incidence is higher in the MSM community, more cases of anal cancer are diagnosed in women than in men.

Despite the growing incidence in anal cancer diagnoses, it is not yet the standard of care to screen for and treat high-grade anal intraepithelial neoplasia (HGAIN), the accepted precursor to anal cancer. The HOST-HGAIN Outcome Study is essential to creating official guidelines for the screening and treatment of anal precancer. As 85-90% of anal cancers are caused by HPV, incidence and death rates would decrease with a screening and treatment protocol that prevents HGAIN from becoming cancer. The CDC's own website for information about preventing HPV-associated cancers states that "there is no approved or recommended screening test for anal or penile cancer because more information is still needed to find out if such tests can be effective." With this study, we have the opportunity to carry out the first ever randomized, controlled trial to change the game for people living with anal precancer.

The HOST-HGAIN Outcome Study has two main objectives: to determine the effectiveness of screening for and treating HGAIN to reduce the incidence of anal cancer in HIV-positive men and women; and to create a bank of blood, anal swab and tissue specimens to support correlative science studies of molecular pathogenesis and biomarkers of progression to anal cancer. If treatment is shown to be effective, we can establish treating HGAIN as the standard of care and reduce the rates of anal cancer. Accepted screening protocols will result in doctors properly trained in necessary diagnostic and screening procedures. Ultimately, more patients will have access to the care that they need.

Other HPV-associated cancers have shown successful decreases in incidence rates when a screening protocol is implemented. Cervical cancer rates, for example, have been reduced by about 80% since screening for and treating high grade cervical intraepithelial neoplasia (HGCIN) became the standard of care.

The biobank component of the study will allow for an improved understanding of other HPV-associated cancers. Over 26,000 new cases of HPV-related cancer are diagnosed every year. This includes cervical, anal, vulvar, vaginal, penile and oropharyngeal cancers. This study will assemble a unique repository of biological specimens that will allow identification of novel biomarkers of disease progression, response to therapy, immune response and molecular pathogenesis. Given the biological similarity between cervical and anal cancer, biomarkers of disease progression identified through this study will also be useful to predict progression to all HPV-associated cancers, including cervical and oral cancer.

We urge you to fund the HOST-HGAIN Outcome Study. Thank you for your consideration.

Sincerely,