



September 20, 2012

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

Dear Members of the Committee:

We write to you as a coalition of organizations committed to improving treatment options for people with human papillomavirus (HPV)-associated malignancies. This letter serves to reiterate our strong support for the high-grade anal intraepithelial neoplasia (HGAIN) Outcome Study (“the HOST”) to improve patient outcomes for people with anal precancer and cancer. We previously sent a coalition letter expressing our support for the HOST on September 8, 2011.

The HOST is essential to creating official guidelines for the screening and treatment of anal precancer. Despite the growing incidence in anal cancer diagnoses in both male and female populations,<sup>1</sup> it is not yet the standard of care to screen for and treat HGAIN, the established precursor to anal cancer. The Centers for Disease Control and Prevention (CDC)’s website for information about preventing HPV-associated cancers states that “[s]creening for anal cancer is not routinely recommended because more information is still needed to find out if screening and follow-up interventions prevent these cancers.”<sup>2</sup> **Since it is not likely that the CDC will update this statement to include screening protocols for anal cancer without data from an approved study, we urge you to approve the HOST as soon as possible.**

<sup>1</sup> Anal cancer is increasing across all populations for both men and women at a rate of two percent a year. In 2012, the National Cancer Institute (NCI) estimates that there will be 6,230 new cases of anal cancer with 3,980 women and 2,250 men diagnosed. In 2011, the NCI estimated that there would be 5,820 new cases.

<sup>2</sup> See <http://www.cdc.gov/std/hpv/stdfact-hpv.htm>. Accessed September 16, 2012.

The HOST will be the first randomized controlled trial to evaluate the efficacy of screening and treating anal precancer. The 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 biobank of blood, anal swab, and tissue specimens to support correlative science studies of novel biomarkers of disease progression, response to therapy, immune response, and molecular pathogenesis. **We hope to decrease the incidence and death rates of anal cancer with an accepted screening and treatment protocol that prevents HGAIN from progressing to cancer.**

The study population will include HIV-positive men and women, a group particularly vulnerable to HPV-related diseases. Although more women than men are diagnosed with anal cancer each year in the general population, the incidence of anal cancer has continued to increase among HIV-positive people since the introduction of antiretroviral therapies.<sup>3</sup> The NA-ACCORD study, the largest study reported to date, showed an incidence of anal cancer of 131/100,000 among HIV-positive men who have sex with men (MSM),<sup>4</sup> which is higher than the highest incidence of cervical cancer in any country. **The American population with HIV continues to increase and 1.2 million Americans currently live with the virus.** There are approximately 48,000 new people diagnosed with HIV each year.

**Furthermore, we expect HPV, which causes 90-95% of anal cancer, and other HPV-related malignancies, including HGAIN, to continue affecting Americans.**

Nationwide, vaccination programs for young women and men are facing challenges. Despite routine recommendations to administer the vaccine for both boys and girls in the United States, HPV vaccination uptake is at 35% for teenage girls and 1% for teenage boys.<sup>5</sup>

The biobank component of the HOST will be valuable in providing an improved understanding of anal cancer, as well as the pathogenesis of other HPV-associated cancers. Over 33,000 new cases of HPV-related cancer are diagnosed every year in the United States.<sup>6</sup> This includes cervical, anal, vulvar, vaginal, penile, and oropharyngeal cancers. Worldwide, HPV-related cancers are a major public health problem. **Given the biological similarity between cervical and anal cancer, biomarkers of disease progression identified through the HOST may also be useful to predict progression in all HPV-associated cancers, including cervical and oropharyngeal cancer.**

Furthermore, it is difficult to undertake such correlative science related to progression

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<sup>3</sup> Crum-Cianflone NF, Hullsiek KH, Marconi VC, Ganesan A, Weintrob A, Barthel RV, et al. Anal cancers among HIV-infected persons: HAART is not slowing rising incidence. *Aids*. 2010 Feb 20;24(4):535-43.

<sup>4</sup> Risk of anal cancer in HIV-infected and HIV-uninfected individuals in North America. Silverberg MJ, Lau B, Justice AC, Engels E, Gill MJ, Goedert JJ, Kirk GD, D'Souza G, Bosch RJ, Brooks JT, Napravnik S, Hessol NA, Jacobson LP, Kitahata MM, Klein MB, Moore RD, Rodriguez B, Rourke SB, Saag MS, Sterling TR, Gebo KA, Press N, Martin JN, Dubrow R; North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) of IeDEA. *Clin Infect Dis*. 2012 Apr; 54(7):1026-34. Epub 2012 Jan 30. See <http://www.ncbi.nlm.nih.gov/pubmed/22291097>. Accessed September 16, 2012.

<sup>5</sup> See <http://www.cdc.gov/vaccines/who/teens/vaccination-coverage.html>. Accessed September 16, 2012.

<sup>6</sup> See <http://www.cdc.gov/cancer/hpv/>. Accessed September 16, 2012.

from high-grade precursor lesions to cancer in the oral cavity or cervix. This is because there is no easily identified oropharyngeal cancer precursor and it is the standard of care to treat cervical high-grade lesions before they progress to cancer.

**We are hopeful that the HOST will lead to protocols that are applied across all populations – both HIV-positive and negative – as the standard of care to treat anal precancer.** The implementation of a screening protocol for another HPV-associated cancer, cervical cancer, has led to improved patient outcomes. It is currently recommended that the biological precursor to cervical cancer, high-grade cervical intraepithelial neoplasia (HGCIN), is treated to prevent it from becoming cervical cancer. **Since cervical cancer screening and treatment were implemented in the United States, cervical cancer rates have decreased by 80%. We anticipate that the HOST will result in a similar positive outcome with respect to anal cancer, and potentially, other HPV-related malignancies.**

In addition, the HOST will result in improved screening, diagnostic, and treatment protocols for health care providers. This can reduce the escalating rates of anal cancer and provide more patients with access to the care they require. In turn, the information provided by the HOST will reduce morbidity in both men and women, in both people HIV-positive and HIV-negative. Furthermore, a recent report by the Institute of Medicine requested by the National Institutes of Health called for more information on the health care needs of the lesbian gay bisexual and transgender communities.<sup>7</sup> Since a high incidence rate of anal cancer affects the MSM community, the HOST will also provide data to better understand and treat the health concerns of that population. **As preventative treatments are less costly overall than treatment of the progressed disease, and given the expense of treating anal cancer and associated morbidity, it is also expected that targeted prevention programs will save healthcare costs for municipal, state, and federal budgets.**

In light of the aforementioned reasons, we strongly urge you to fund the HOST, which will save both financial resources and many human lives. Thank you for your timely consideration of this matter.

Sincerely,



Justine, Tristan and Camille Almada  
Co-Founders  
The HPV and Anal Cancer Foundation



Stephen Goldstone  
Vice President  
International Anal Neoplasia Society

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<sup>7</sup> *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding*. Institute of Medicine. March 31, 2011. See <http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx>. Accessed September 16, 2012.

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A handwritten signature in black ink that reads "Monica Rodriguez". The signature is written in a cursive, flowing style.

Monica Rodriguez  
President & Chief Executive Officer  
Sexuality Information and Education  
Council of the United States (SIECUS)