Clinical Trials Update

**Principal Investigator:** Carlos Ramos, Center or Gene and Cell Therapy  
**Other HNC Program Co-Investigators:** Andrew Sikora, Anita Sabichi, Jun Zhang, Cliona Rooney, Stephen Gottschalk

**Type of Trial:** Investigator initiated, therapeutic, phase 1  
**Status:** Open and accruing patients (as of 9/13/15)  
**Eligible Patients:** Recurrent or refractory, HPV-associated malignancy (primarily head and neck, but also anogenital cancer)

Contact for information or patient referral: Vicky Torrano, RN  
(vxtorran@txch.org)

Human papilloma viruses (HPVs) are associated with cancers of the head and neck, uterus (cervical cancer), vulva, penis and anus. The virus makes proteins in the tumor cells that should allow the diseased cells to be recognized and killed by a part of the body's own immune system called T cells. Unfortunately, tumors are able to avoid being killed by making molecules that turn off these T cells.

We have previously studied cancers caused by a different virus called Epstein-Barr virus (EBV). These EBV-cancers are like HPV-cancers, since they turn off the T cells that would otherwise destroy them, and so can keep growing. We found, however, that if we removed the T cells from the blood of patients with EBV-cancers and grew them outside the body, we could increase the number and the activity of T cells directed against the tumors. When these T cells were given back to the patients, they eliminated the cancers in over half the recipients. Unlike chemotherapy, radiation and surgery, the side effects of this treatment were minimal.

We now want to repeat this approach in patients with HPV-cancers in new clinical protocol called HESTIA. We have discovered a way to grow large number of HPV-specific T cells from the blood of patients with HPV-cancers. These T cells are able to recognize and kill HPV-bearing cells and we plan to return them to patients with HPV-cancers to see if they produce a benefit. The type of treatment we propose will thus be a new and potentially life-saving treatment for HPV-related cancer.

Mini-Grant Opportunity

http://www.bcm.edu/hncancerprogram  
Dan L. Duncan Cancer Center
Squamous cell carcinoma of the head and neck (HNSCCA) is the fifth most common cancer worldwide and a significant public health problem in both the developed and developing world. The BCM Head and Neck Cancer Program will offer two seed grants to jump-start innovative pilot projects focused on developing new approaches to the treatment, diagnosis, and management of HNSCCA and other cancers of the head and neck (including thyroid and salivary cancers). Projects should be translational in intent, with the potential to lead to new clinical approaches, and should be clearly related to one of the three Head and Neck Cancer Program focus areas:

1. Cancer immunotherapy and HPV related cancers.
2. Personalized/precision cancer medicine.

Details:
- Two pilot grants of up to $25,000
- Applications accepted starting Nov. 1, deadline is Nov. 17, 2015
- Period of implementation is 12 months, beginning Jan. 1, 2016

Please contact Kiko Risteski at hristijan.risteski@bcm.edu for more information, or refer to the complete RFA.

Guest Lecture: Andrew Shuman, MD

Dr. Shuman, Assistant Professor at the University of Michigan Medical School, is a head and neck surgeon with additional specialization in medical ethics. He is Chair of the Adult Ethics Committee and Consultation Service for the University of Michigan Health System, and also a core faculty member in the Center for Bioethics and Social Sciences in Medicine. Dr. Shuman completed residency in Otolaryngology at University of Michigan, and then went on to a Fellowship in Medical Ethics at Weill Cornell Medical College and Surgical Oncology Fellowship at Memorial Sloan-Kettering Cancer Center.

The Head and Neck Cancer Program, Department of Otolaryngology, and Dan L. Duncan Cancer Center are jointly sponsoring an upcoming lecture addressing social and ethical implications of personalized medicine:

“Getting Personal: Treating head and neck cancer in the era of precision medicine”
Thursday, October 22, 2015
Alkek Building N315
5:00pm - 6:00pm

Monthly Head and Neck Cancer Meeting
- Wednesday, Oct. 14, 2015 at 5pm in Neurosensory Center NA511 Conference Room
- Wednesday, Nov. 11, 2015 at 5pm in Neurosensory Center NA511 Conference Room
- Wednesday, Dec. 9, 2015 at 5pm in Neurosensory Center NA511 Conference Room
Recently Awarded Research Grants

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<td>Jennifer Hwang (consultant: Elizabeth Chiao, MD, MBA)</td>
<td>“Human papillomavirus (HPV)-associated second malignancies in patients who receive allogenic stem cell transplantation</td>
<td>Duncan Family Institute Seed Funding from MD Anderson Cancer Center</td>
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<td>Julina Ongkasuwan, MD, FAAP, FACS Co-I: Andrew Sikora, MD, PhD Donald T. Donovan, MD, FACS Kenneth Altman, MD, PhD, FACS</td>
<td>Treatment Alternatives in Adult Rare Disease: Assessment of options in idiopathic subglottic stenosis: NOAAC PR-02 study</td>
<td>Patient-Centered Outcomes Research Institute (PCORI)</td>
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<td>Fredrick A. Pereira, PhD</td>
<td>Mechanism of PEG-HCC nanoparticles enhancement of auditory acuity</td>
<td>The Dunn Foundation</td>
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<td>Andrew Sikora, MD, PhD</td>
<td>Cancer Research Institute Strategy Team Grant: Targeting tumor microenvironment to enhance immune-stimulating effects of chemoradiotherapy</td>
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<td>Andrew Sikora, MD, PhD Co-I: Elizabeth Chiao, MD,MBA Michael Scheurer, PhD, MPH</td>
<td>Initial ex-vivo clinical validation of dendritic cell-targeting therapeutic HPV vaccine for HIV-positive</td>
<td>Collaborative Faculty Research Investment Program</td>
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<tr>
<td>Andrew Sikora, MD, PhD Collaborator: Elizabeth Chiao, MD, MBA</td>
<td>Validation of novel monoclonal antibodies targeting HPV-associated cancers</td>
<td>Dan L. Duncan Cancer Center Pilot Project Grants</td>
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Publications


Moskalenko, Marina, Michael Pan, Yichun Fu, Ellen H. de Moll, Daigo Hashimoto, Arthur Mortha, Marylene Leboeuf, Andrew G. Sikora, et al. 2015. “Requirement for Innate Immunity and CD90+ NK1.1− Lymphocytes to Treat Established Melanoma with Chemo-Immunotherapy.” *Cancer Immunology Research* 3 (3): 296–304. doi:10.1158/2326-6066.CIR-14-0120. [PMID:25600438](http://dx.doi.org/10.1158/2326-6066.CIR-14-0120)


Wenaas, Ashley E., Brandon Tran, and Julina Ongkasuwan. 2015. “The Progression of Thyroid Cartilage Calcification as It Relates to the Utilization of Laryngeal Ultrasound.” *The Laryngoscope*, September, n/a – n/a. doi:10.1002/lary.25582. [onlinelibrary.wiley.com](http://onlinelibrary.wiley.com)