<u>Salivary Biomarkers Development for Detection of Lung Cancer</u>, Principal Investigator, David Wong, Ph.D. (20PT-0032)

Lung cancer is the leading cause of cancer death for both men and women (http://www.cancer.gov/cancertopics/types/lung)

In 2009, 219,440 new lung cancer patients were diagnosed in the U.S., and roughly 87% were non-small cell lung carcinomas (NSCLC). Smoking, particularly of cigarettes, is by far the main contributor to lung cancer. In the U.S. it is estimated that there are 45 million current and 45 million former smokers at risk for developing lung carcinoma and this disease is estimated to remain a major global health problem for at least the next 50 years. Over 75% of lung cancer cases are diagnosed in late stages because there remains no practical way to screen a large number of people at risk. The poor results in NSCLC treatment can be attributed to factors including non-responsiveness to chemotherapy and radiation therapy, late presentation of the lesions, and the lack of biological markers for the early detection. These results are clearly disappointing and point to the need for new strategies to help control the disease. Early detection offers the promise of improved cure rates. Strategies to identify high-risk individuals are sorely needed. The dilemma remains how to efficiently facilitate stratification to appropriately identify these individuals.

This Integrated Research Project Award proposal titled "Salivary Biomarker Development for Detection of Lung Cancer" is responsive to the objective of the TRDRP's to perform pivotal and definitive validation of innovative technologies that have been proven in principle to have capability to detect lung cancer in human using non-invasive biological samples. Saliva fulfills this objective. The applicant research team is the leading research team in salivary diagnostics funded by the National Institute of Health to develop salivary biomarker and point-of-care biosensor platform technologies. Proof of concept data is in place to support that salivary biomarkers can detect human lung cancer. This Integrated Research Project Award application is to perform the definitive and pivotal human clinical validation study.

The holy grail of diagnostics is non-invasiveness. Saliva fulfills this goal. This transformative goal is echoed by a national initiative from President Obama that mandates the "Detecting dozens of diseases in a sample of saliva" as one of the 14 Grand Challenges for biomedical research in the 21st Century [93].

We are the most competent team to meet this challenge. This TRDRP application will mature and advance salivary diagnostics to be a scientific credible and compelling biofluid for molecular diagnostics and transforming molecular diagnostics to the juncture where dozens of systemic diseases can be detected in a sample of saliva.