Innovative Technologies for the Early Detection of Lung Cancer: Validation in Human Cohorts: A Special Integrated Research Project Initiative

A. Objective

The objective of this initiative is to validate innovative technologies that have already been proven in principle to have the capability of detecting lung cancer in humans using non-invasive biological samples such as saliva, expired air, blood, serum or urine. Projects are expected to be collaborative efforts between researchers with specific technological expertise in biomarker identification and/or pattern recognition and clinical researchers with expertise in lung cancer diagnosis as well as access to clinical cohorts of demographically-appropriate men and women at high risk of lung cancer. Biospecimens used for validation can be collected either within the context of existing CT screening trials of high-risk individuals or as part of the new or ongoing development of a high-risk clinical cohort.

B. Background

Lung cancer is by far the leading cause of cancer-related mortality in the US with 159,390 deaths predicted for 2009. California can expect the second highest number of estimated new cases (17,910) in the US, only slightly less than Florida (17,970). Lung cancer's public health burden is exacerbated by striking disparities that exist in both disease incidence and disease survival among different ethnic groups within the US, with African-American males bearing the heaviest burden. The lung cancer incidence rate is 36% higher in African American men than in white men and death rates due to lung cancer are 30% higher. Lung cancer diagnosis is almost invariably made after symptoms have appeared, at which point the cancer is frequently well advanced and difficult to treat successfully. If the tumor is detected early enough, the patient's 5-year survival rate rises dramatically from 15% to 45%. Early detection is thus key to successful treatment. To date no specific biomarker or biomarker panel is available for clinical diagnosis of early lung cancer, despite the clear need for such a tool in the management of this disease. Because a pressing need exists for transformative research to develop non-invasive methodologies that detect pre-clinical lung cancer in all ethnic groups, particularly those at greatest risk, TRDRP is launching an initiative to assist ongoing efforts in this regard. The ultimate objective is to alleviate the public health burden of lung cancer, a disease that cost $10.3 billion in health care expenditures in 2006.

C. Eligibility Criteria

Proposals must identify a principal technical investigator with expertise in biomarker detection and/or identification and at least one collaborating clinical investigator with expertise in lung cancer. The clinical partner must have access to a cohort or cohorts of demographically appropriate men and women at high risk of lung cancer. The collaborating clinical entity must be capable of a) enrolling the required number of participants meeting eligibility requirements, including the documentation of known pathologies and conditions that might affect donor specimen sample quality and b) providing both case and normal samples to the technical investigator. The clinical institution will be required to document that their patient

population/cohort includes an ethnically diverse population, including African Americans in particular.

The principal and collaborating investigator(s) must qualify, at the time of submission of qualifications, for that status under their research institutions' policies.

D. Award Details

The TRDRP has set aside $1,250,000 per year for this Special Initiative on Innovative Technologies for the Early Detection of Lung Cancer. TRDRP anticipates funding up to four awards at this time. Integrated Research Project Awards for this Special Initiative can be made for up to **three years,** with continued funding evaluated on a yearly basis by an outside panel of experts. Annual direct costs are capped at **$260,000**. Allowable expenses include salaries, fringe benefits, supplies, equipment, and domestic travel. Travel to scientific meetings is restricted to $2,000 per year. Indirect costs for institutions other than UC campuses will be allowed and should be considered in addition to the direct costs for the award. TRDRP will pay indirect rates to the researcher's institution based on the institution's federally established rate.

E. Contact Information

Inquiries pertinent to this RFA should be directed to:

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