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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Cooperative Research and Development Agreement (CRADA) Opportunity for Development of an Assay to Detect Genetic Markers Related to Elevated Serum Tryptase in Familial Tryptasemia and Mast Cell Activation Disorders

ACTION: Notice

SUMMARY: The National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), Department of Health and Human Services (HHS) seeks to enter into a CRADA with a commercial partner to collaborate on the development and commercialization of an assay to detect a genetic variation related to mast cell activation disorders.

DATES: Interested CRADA collaborators must submit a confidential proposal summary to the NIAID (attention Amy F. Petrik at the address below) on or before 8 June 2016 for consideration. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest. CRADA proposals submitted thereafter may be considered if a suitable CRADA collaborator has not been selected.

ADDRESSES: Questions should be addressed to Amy F. Petrik, Ph.D., Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, Rockville, MD 20892-9804, Tel: (240) 627-3721 or email: petrika@niaid.nih.gov.

SUPPLEMENTARY INFORMATION: Approximately 4-6% of the general Western population exhibit elevated basal levels of serum tryptase. As a mast cell mediator, tryptase is expected to be transiently elevated following allergic stimuli. Sustained elevation of serum tryptase levels can be associated with symptoms of mast cell mediator release (such as flushing, itching and swelling), neuropsychiatric symptoms (such as chronic pain, anxiety and dysautonomia) and gastrointestinal (GI) symptoms (including functional GI disorders like irritable bowel syndrome as well as eosinophilic GI disease) as well as an increased risk for systemic anaphylaxis.

The NIAID Investigators have recently reported that these symptomatic tryptase elevations can be inherited in an autosomal dominant fashion and are associated with the phenotype described above (Lyons, J.J., et al. J Allergy Clin Immunol, 133 (2014), pp. 1471-1474). Through next generation sequencing and linkage analysis the NIAID Investigators identified a structural variant cosegregating with disease. They then developed an assay, based on digital droplet PCR, to identify individuals with this variant, and estimate that 5-8% of Caucasians may have it, and be at risk for being symptomatic.

Under the CRADA, the assay will be developed toward licensure. Due to the relatively high prevalence of serum tryptase elevation, NIAID Investigators anticipate receiving a large number of samples for analysis which would exceed their capacity. A collaborator with the expertise and capacity for implementing a CLIA or FDA approved test for this genetic variant is sought.

A Cooperative Research and Development Agreement (CRADA) is the anticipated collaborative agreement to be entered into with NIAID pursuant to the

Federal Technology Transfer Act of 1986, codified as 15 U.S.C. § 3710a, and Executive Order 12591 of April 10, 1987, as amended. A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government laboratories. A CRADA is not a grant, and it is not a contract for the procurement of goods/services. The NIAID is prohibited from transferring funds to a CRADA collaborator. Under a CRADA, NIAID can contribute facilities, staff, materials, and expertise. The CRADA collaborator can contribute facilities, staff, materials, expertise, and funds. The CRADA collaborator will also have an option to negotiate the terms of an exclusive or non-exclusive commercialization license to subject inventions arising under the CRADA. The goals of the CRADA include the rapid publication of research results and timely commercialization of products, diagnostics, and treatments that result from the research.

The expected duration of the CRADA with be two (2) to three (3) years.

Date: April 2, 2016

Suzanne Frisbie, Ph.D.

Deputy Director

Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases

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