Concept Clearance: NCI-NIAID Serological Sciences Network for SARS-CoV-2

Lewis-Burke Associates LLC – May 13, 2020

On May 12, 2020, the National Cancer Institute (NCI) Board of Scientific Advisors held their Advisory Council meeting and announced a Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) concept based on a collaboration between NCI and the National Institute of Allergy and Infectious Disease (NIAID). The purpose of this concept clearance is to mobilize collaborative efforts to rapidly expand national testing capacity. This appears to be the first concept clearance for Coronavirus Disease 2019 (COVID-19) related research considered and approved by an NIH Institute Advisory Council.

The proposed serological sciences network for SARS-CoV-2 would contain five components. The Frederick National Lab (FNL) Serology Lab would serve as the core lab, mainly validating serological tests for SARS-CoV-2. Capacity Building Centers will be funded to focus on developing and expanding serological testing capacity and practices in the community. Serological Centers of Excellence and Serological Sciences Projects will be funded to understand the mechanisms driving serological, humoral, and cellular immune responses to SARS-CoV-2 viral infection to inform the development of novel serological tests. Lastly, the National Coordinating Center at the Frederick National Lab will manage, coordinate, and provide communication across the Serological Sciences Network for SARS-CoV-2. There will be a preference for a cancer relevant component when funding the centers of excellence and the serological sciences projects.

Potential Award Information: Funding opportunities will be available for three of the five components within the network.

- **Funding for the Capacity Building Centers** will be provided through a contract mechanism. NCI anticipates awarding between four and eight academic and/or private sector organizations with funding up to $3 million in total costs per year for each site for up to five years.
- **Funding for the Serological Centers of Excellence** will be funded through the Specialized Center – Cooperative Agreements (U54) mechanism. An estimated four to eight centers will be funded for awards up to $2 million in total costs per year for up to five years.
- **Funding for the Serological Sciences Projects** will be funded through the Research Project – Cooperative Agreements (U01) mechanism. An estimated five to ten investigators will be awarded with grants up to $500,000 in total costs per year for up to five years.

Next Steps: NCI plans to publish a Notice of Intent to Publish as well as a Request for Information (RFI) seeking input on the strategy for research in Coronavirus Serology Testing and Serological Sciences within the coming weeks. The RFI will remain open for comment for ten days and responses will be reviewed and incorporated into the design and scientific scope of the network. NCI plans to use the Emergency Funding Opportunity Announcement authorization to expedite the publication of this opportunity. Once the funding opportunity announcement is published, investigators will likely be given four to six weeks to prepare and apply. NCI expects to make awards by September 2020.

Sources and Additional Information: