Serological Science for COVID-19

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Supplemental funding from Congress

- Enacted April 24th
- $306M for NCI to develop, validate, improve, and implement serological testing and associated technologies
- COVID-19 focused and distinct from annual appropriation; not in RPG
Proposed Serological Sciences Network for SARS-CoV-2

4-8 CBCs: Serological Sciences Capacity Building Centers (RFP)

4-8 U54s: Serological Sciences Centers of Excellence (RFA)

5-10 U01s: Serological sciences projects (RFA)
FNLCR Serology Lab

- Implement and qualify SARS-CoV-2 ELISA assays for IgM, IgG and IgA
- Rapidly identify, procure, and characterize serum/plasma specimens from SARS-CoV-2 patients and necessary controls
  - To allow comparison of negative, medium and high response levels
- Establish panels and produce novel reagents for qualification/validation of SARS-CoV-2 serological and other relevant immune assays and distribute to the network
- Develop qualified assay standards for the serology community
Serological Sciences Capacity Building Centers

Goals
• Develop and expand serological testing capacity and practice in the community
  • Implementation of serological standardization, assay development and availability of FDA-EUA authorized SARS-CoV-2 testing to identify those who may have been exposed to the virus.
  • Scale up acquired serological testing to provide increased national capacity by screening at least 10,000 patients per week with FDA-EUA authorized assays
• Acquire convalescent sera from recovered COVID-19 patients who are seropositive and conduct surveillance clinical trials in patients who have recovered from COVID-19 and are seropositive
• Pursue focused serological science

RFP
4-8 contracts with academic and/or private sector through FNLCR
Up to $3M total costs per year, per site
Serological Sciences Centers of Excellence (RFA)

**Goals**
- Understand the mechanisms driving the serological, humoral and cellular immune responses to SARS-CoV-2 viral infection to inform the development of novel serological tests
- Determine the serological correlates with disease pathogenesis and protection against future infection
- Improve population-based models of outbreak and susceptibility through serology-focused studies
- Preference for cancer relevant component

Each Center will have 2-3 projects, administrative core and the possibility of technical core

*Budget set-aside for collaborative projects proposed post-award*
Serological sciences projects (RFA)

5-10 U01 awards

Up to $500K total costs per year, up to 5 years

Goals

• Understand the mechanisms driving the serological, humoral and cellular immune responses to SARS-CoV-2 viral infection to inform the development of novel serological tests
• Determine the serological correlates with disease pathogenesis and protection against future infection
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Budget set-aside for collaborative projects proposed post-award
Network Coordinating Center at Frederick National Lab

Goals

• Provide program management, coordination and communication across the Serological Sciences Network for SARS-CoV-2

• Coordinate sharing of the data, reagent, sample, and assays

• Coordinate comparison of results among different centers and assays through inter-Center collaborative studies, leading to international serology standardization

• Coordinate partnerships with national and international associates such as the FDA, CDC, WHO, National Institute for Biological Standards and Control (NIBSC), and others

• Work in close collaboration with NCI program staff
Request for Information:
Strategy for Research in Coronavirus Serology Testing and Serological Sciences

• Seeking input from the research community on scope of Serological Sciences Network
• RFI will be open to response for 10 days
• Responses will be reviewed and incorporated into the design of the technological and scientific scope of the Network
The Serological Sciences Network

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