

Serological Science for COVID-19

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4th Virtual Meeting of the Board of Scientific Advisors

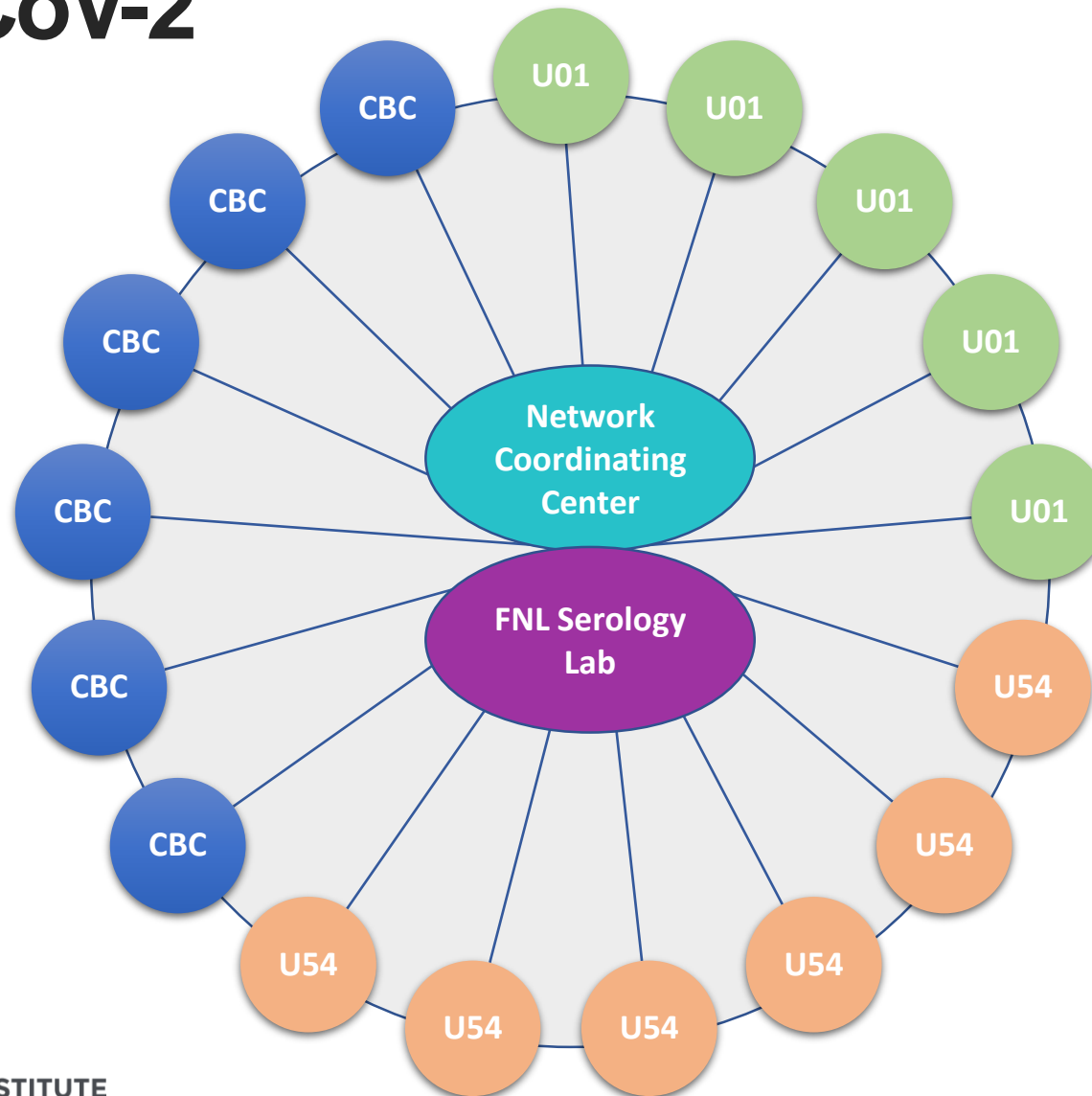
May 12, 2020

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

134 STAT. 620	PUBLIC LAW 116-139—APR. 24, 2020
	Public Law 116-139 116th Congress
	An Act
Apr. 24, 2020 [H.R. 266]	Making appropriations for the Department of the Interior, environment, and related agencies for the fiscal year ending September 30, 2019, and for other purposes.
Paycheck Protection Program and Health Care Enhancement Act. 15 USC 9001 note.	<i>Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,</i>
	SECTION 1. SHORT TITLE.
	This Act may be cited as the “Paycheck Protection Program and Health Care Enhancement Act”.
	SEC. 2. TABLE OF CONTENTS.
	The table of contents for this Act is as follows:
	Sec. 1. Short title. Sec. 2. Table of contents. Sec. 3. References.

Proposed Serological Sciences Network for SARS-CoV-2



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

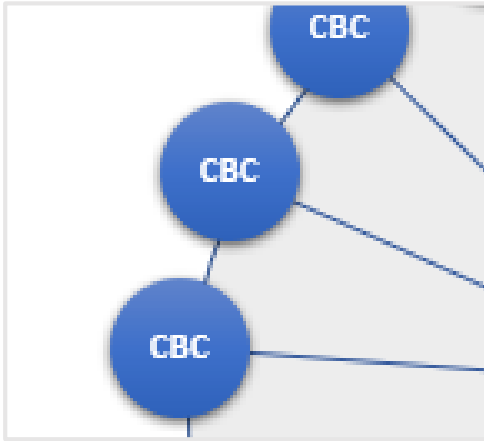
4-8 U54s: Serological Sciences Centers of Excellence (RFA)

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



RFP

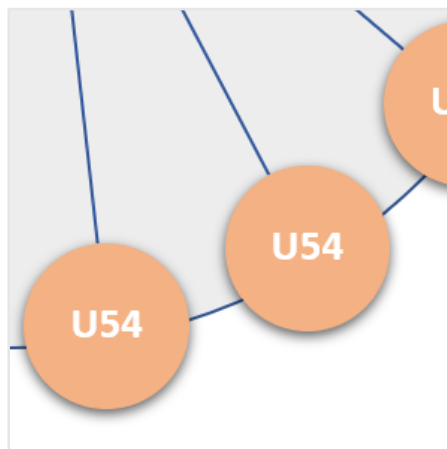
4-8 contracts with academic and/or private sector through FNLCR

Up to \$3M total costs per year, per site

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

Serological Sciences Centers of Excellence (RFA)



4-8 U54 awards

Up to \$2M total costs per year for up to 5 years

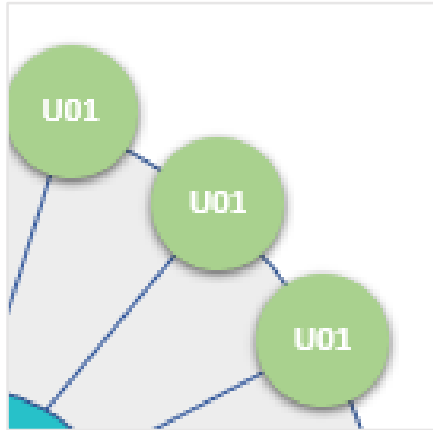
Goals

- 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
- 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
- Improve population-based models of outbreak and susceptibility through serology-focused studies
- Preference for cancer relevant component

Budget set-aside for collaborative projects proposed post-award

Network Coordinating Center at Frederick National Lab



Network
Coordinating
Center

**FNLCR Task
Order**

**\$750K total
costs per year**

Goals

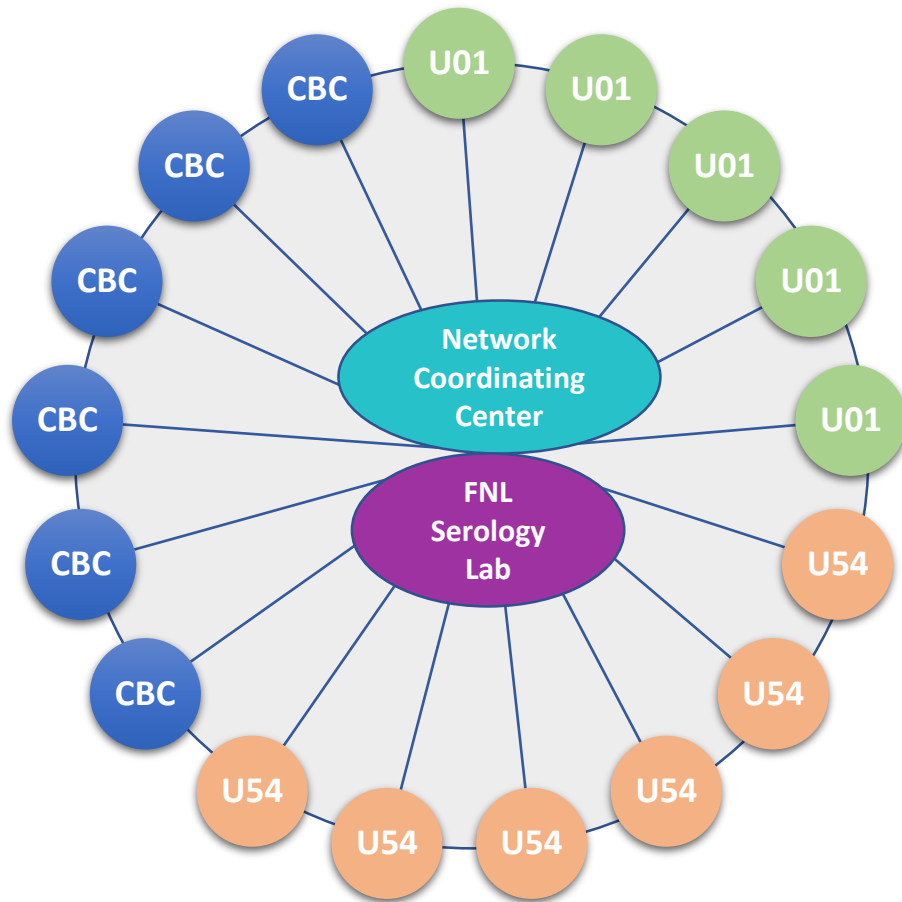
- Provide program management, coordination and communication across the Serological Sciences Network for SARS-CoV-2
- Coordinate sharing of the data, reagent, sample, and assays
- Coordinate comparison of results among different centers and assays through inter-Center collaborative studies, leading to 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



With Special Thanks to:

NCI

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