

Frederick National Laboratory for Cancer Research

CONTRACT RECOMPETITION CONCEPT REVIEW

Sara S. Hook, Ph.D.

Associate Director, NCI-Frederick

- FNLCR 101: The basics
- A critical component of the research enterprise
- Envisioning the future

FNLCR is a Federally Funded Research and Development Center (FFRDC).

FFRDCs are sponsored under a broad charter by a Government agency (or agencies) for the purpose of **performing, analyzing, integrating, supporting, and/or managing basic or applied research and/or development** and that receive 70% or more of their financial support from the Government.

42 research centers share the FFRDC designation, including:

- **Center for Naval Analyses (DoD)**
- **National Center for Atmospheric Research (NSF)**
- **Los Alamos National Laboratory (Energy)**
- **Homeland Security Institute (DHS)**

FNLCR is the only FFRDC dedicated solely to **biomedical research** and among the **largest contracts in HHS.**

FNLCR: One contract, many constituents



FFRDC contracts differ from most government contracts.

Parameters associated with an FFRDC:

- Meets some **special, long-term R&D need** which **cannot be met as effectively** by existing in-house or contractor resources
- Must **operate in the public interest**, free from conflicts of interest
- Have **access beyond the normal** contractual relationship
- **Should not compete with the private sector**
- Periodic reviews are required to renew the sponsoring agreement to determine that the **criteria for establishing the FFRDC continue** to be satisfied.

See Federal Acquisition Regulation (FAR) 35.017

Frederick National Lab is not a single lab

FNLCR is part of NCI Frederick:

- 68-acre campus in Frederick, Maryland
- Surrounded by *but not part of* Fort Detrick
- ~100 buildings house FNLCR labs, NCI labs, research services, and administrative offices



Several FNLCR programs are housed at the Advanced Technology Research Facility

- 330,000 sf, opened in 2012
- 5 miles from main NCI Frederick campus

Altogether, NCI Frederick has

- ~ 2,200 FNLCR staff employed by the current contractor
- ~ 750 federal employees

FNLCR Key Features

STRATEGIC RESEARCH

Pursues new scientific opportunities through flexible, rapid, collaborative approaches

Scientific projects are developed based on the opportunities, needs, and resources

RIGOROUS PROJECT REVIEW

Major projects under consideration are approved by one or more NCI (or other NIH Institute or Center) Advisory Boards:

**FREDERICK NATIONAL
LABORATORY ADVISORY
COMMITTEE (FNLAC)**

**BOARD OF SCIENTIFIC
ADVISORS**


**NATIONAL CANCER
ADVISORY BOARD**

ONGOING PROGRESS REVIEWS

FNLAC

-Working groups & sub-committees, task force as appropriate

**BOARD OF SCIENTIFIC
COUNSELORS**



Frederick National Laboratory for Cancer Research:

A critical component of
the research enterprise

FNLCR Achievements

Over 400 NIH-sponsored clinical trials per year

Produced over 130 biopharmaceutical products (over 60 in clinical trials)

Produced 70 lots of clinical products in the last five years through **two cGMP manufacturing programs**

Characterized over 440 candidate nanoformulations

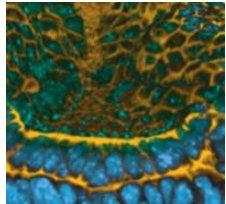
Developed first test to screen nation's blood supply for HIV

Sample projects supported

- National Center for Advancing Translational Sciences Therapeutics for Rare and Neglected Diseases (NCATS TRND)
- NCI Molecular Analysis for Therapy Choice (NCI-MATCH)
- Cancer Moonshot
- The Cancer Genome Atlas (TCGA)
- Human Papillomavirus (HPV) Serology Laboratory
- Partnership for Research on Ebola Vaccines in Liberia (PREVAIL)
- Genotype-Tissue Expression Project (GTEx)
- Clinical Proteomic Tumor Analysis Consortium (CPTAC)
- Genomic Data Commons (GDC)

Science and Technology at FNLCR

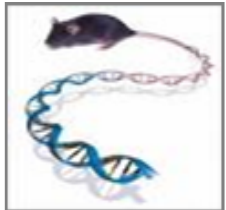
The Frederick National Lab is dedicated to improving human health through discovery and innovation in the biomedical sciences, focusing on cancer, AIDS, and emerging infectious diseases.



Basic, translational, and clinical science

Cancer, HIV/AIDS, and cancer viruses

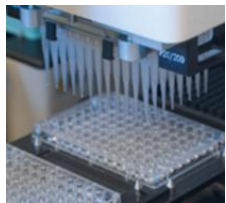
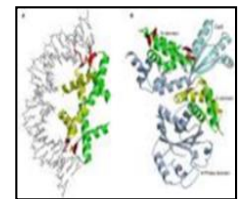
Data sciences



Biopharmaceutical and vaccine development

Drug discovery

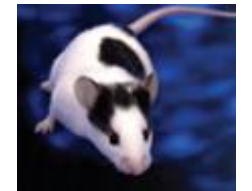
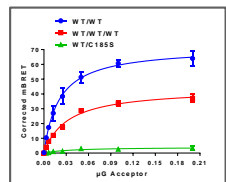
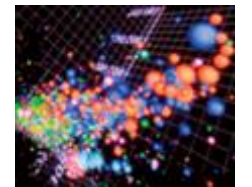
Reagent validation and characterization



Animal models and biomedical imaging

Nanotechnology characterization and formulations

Optical & Electron microscopy, Cryo-EM



RAS Initiative Collaborations: Hub and Spokes

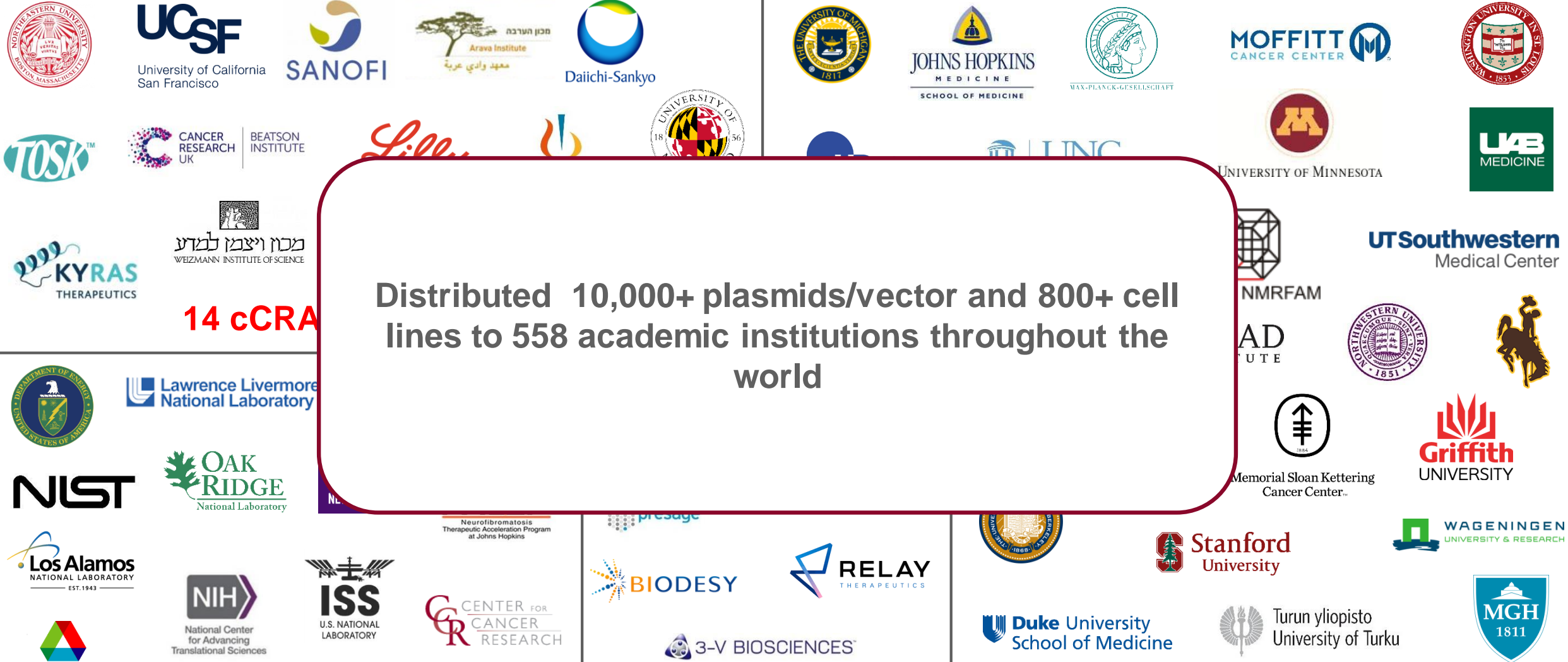
Distributed 10,000+ plasmids/vector and 800+ cell lines to 558 academic institutions throughout the world

14 cCRA

12 Strategic Collaborations

5 Industry Collaborations

27 Academic Collaborations



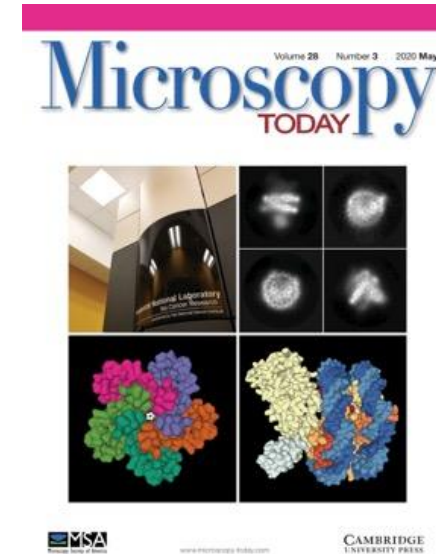
National Cryo-EM Facility – the first three years

Over 370 cancer-related data collections from 39 institutions.

More than 25 NCEF supported publications in journals like Nature, Science, Cell, Nature Communications, PNAS, and NSMB.

Prioritized COVID-19 data collections

Paper in Microscopy Today describing best practices used in the facility.



COVID-19

SeroNet Coordinating Center



CBC Site U54 Site U01 Site

Clinical Serology National Standards

Reference standards for antigen positive plasma

Protein Expression Lab

Provided spike proteins for seroprevalence and other studies. Additionally, screened 2,000 tethering fragments to identify those that bind to active site cysteines in essential proteases.

With Argonne National Lab.

NCI/FDA SARS-CoV-2 Serology Validation Program

- Evaluation of ELISA assays and Lateral Flow Devices
- specificity and sensitivity

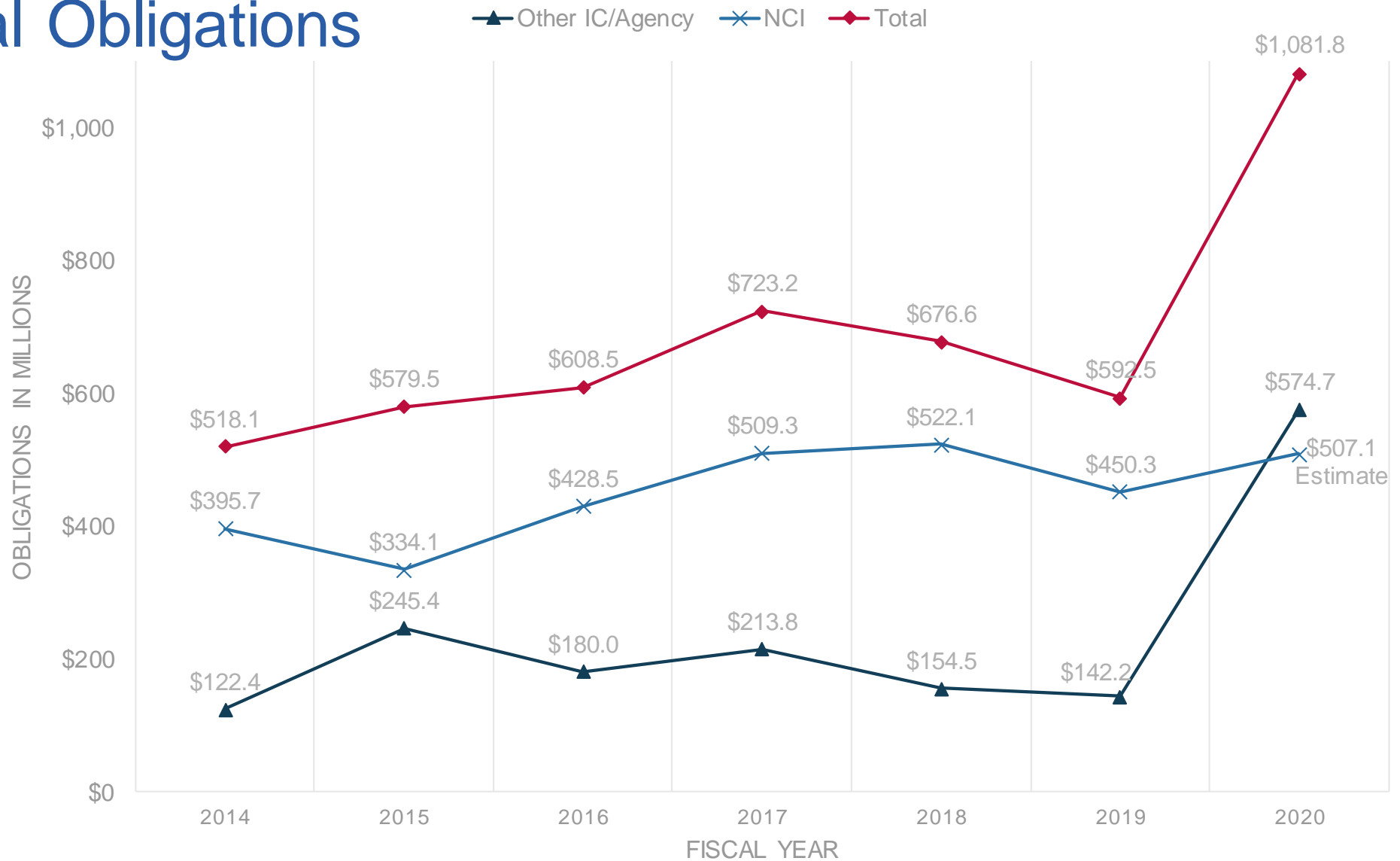
Clinical Trials with NIAID

- ACCT-Remdesivir
- ACTIV-3 part of Operation Warp Speed (inpatient) multiple neutralizing mAb
- ACTIV-2 Outpatient mAb with other therapies
- Mexico, Indonesia, Mali, Liberia, Guinea

Serosurveillance Studies with NIH All of Us

Screening 40,000 serum samples for SARS-CoV-2 antigens as a measure of early exposure

Historical Obligations



Note: In addition to the NCI annual appropriations displayed by the red line, NCI also obligated the following gift, CRADA, royalty and Moonshot amounts on the Leidos contract: FY 2014 = \$24.8M ; FY 2015 = \$19.0M ; FY 2016 = \$60.4M; FY 2017 = \$153.3M; FY 2018 = \$107.3M; FY 2019 = \$65.3M; FY 2020 Estimate = \$69.0M



Envisioning the future

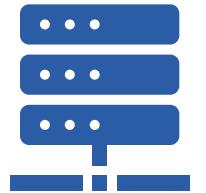
What will FNLCR do to advance biomedical research needs in the future?

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FUNDAMENTAL TASKS

NOT-CA-21-018 RFI new ideas for next national mission program, closes Jan. 18, 2021

- Provide to NCI-supported investigators access to services, tools, and resources not readily available to individual labs
- Serve as a hub for technology development
- Function as a nucleus for large-scale projects



How will FNLCR best support research in the years ahead?

Pursue **high risk/high reward projects**

Maintain a **full intellectual, scientific partnership** with the NIH

Build **relational bridges** and work as a team with partners for **shared success**

Nurture a spirit of **organizational excellence**

Operate in a **flexible, transparent, accountable** and **effective** manner

Demonstrate **boldness and creativity** in ideas and execution

FNLCR Contract Recompetition Process

December
2020

~August
2023



**BSA
Concept
Review**

**Pre-
Solicitation
Activities**

**Solicitation/
Request for
Proposals**

**Evaluation
of Proposals**

Negotiations

**Contract
Award**

Discussion and thanks!

Kristin Komschlies – FFRDC COR
Lisa Coleman – Head Contracting Officer
Jim Cherry
Don Mills
Paulette Gray
Kelli Marciel
Nancy Murphey
Laura McNay, NIAID



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