Overview of FNLCR
Process, Progress, and Programs
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Overview of Frederick National Laboratory for Cancer Research

FNLCR is the only Federally Funded Research and Development Center (FFRDC) dedicated exclusively to biomedical research

- Proudly operated in the public interest by Leidos Biomedical Research, Inc (formerly SAIC-Frederick) on behalf of the National Cancer Institute

Main campus located on 70 acres at Ft. Detrick, MD

- Leidos Biomed employees co-located with NCI researchers and other contractors on the NCI Campus at Frederick
- Additional Leidos Biomed scientists at Bethesda and Rockville sites

Mission

Provide a unique national resource for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis and treatment of cancer and AIDS.
• The FFRDC provides the NCI unique acquisition and response capabilities, including:
  – **Flexibility** – due to the broad charter and use of contractor staff
  – **Rapid Response** – new or cutting edge projects can be accomplished more expeditiously.
  – **Increased Efficiency** – due to
    • broad latitude in subcontracting
    • unforeseen work can be added without additional fee, indirect/infrastructure cost, or contract administration or oversight.

• The FFRDC designation requires FNLCR to meet the NCI’s rapidly changing needs that cannot be achieved *as effectively* by other NCI components or through other government mechanisms.
A wholly-owned subsidiary of Leidos Holdings, Inc., solely dedicated to one mission:

Frederick National Laboratory for Cancer Research

The staff of FNLCR are employees of Leidos Biomedical Research, Inc.
Securing the Future
Helping make our communities, our nation and our world a better place for generations to come.

Health
Advancing health technology to improve patient care, reduce healthcare costs, and enhance public health.

National Security
Delivering innovative solutions that help protect freedom in all domains — air, land, sea, space and cyberspace.

Engineering
Passionate about protecting our environment and making energy supply and delivery smarter, cleaner, and more reliable.
Interplay between Leidos Biomedical Research and our Corporate Parent

$ - Award Fee

Reference Quals

Biomedical R&D Expertise

Owned by

$ - Non-allowable costs

Legal & Financial Oversight

IT & Big Data Expertise
Individual Divisions, Offices, and Centers decide how much of their budgets they want to spend on FNLCR science and services

- Infrastructure, management oversight, and shared services are funded by the Office of the Director
- Virtually all other staff are “dedicated” to the DOC that funds them

Changes in work at FNLCR are performed through an electronic approval called a “Yellow Task”

- Initiated by a government “customer”, the request is vetted for suitability for FNLCR by the Project Officer and the Contract Officer (both are NCI)
- The appropriate FNLCR program develops a budget and workplan with the customer
- Plan and budget are approved by customer and the Administrative Officer (NCI) and the OTS contract is modified to reflect change in funding

Yellow Tasks by the numbers (FY13)

- 195 YTs submitted by 23 divisions, institutes, and other government agencies
- Total value of all cost estimates approved - $243 Million (spanning up to 5 years)
- Average YT turnaround time : 38 days (range 4 to 160)
- YT-13-072 – “KRAS Startup Initiative” – Approved Apr 1, 2013 (13 days)
FNLCR OTS Contract
FY13 Estimated Cost

NCI Appropriated
Total: $299.2 Million

CBIIT, $11.7 mio, 4%
OD-CSSI, $11.1 mio, 4%
DCEG, $20.0 mio, 7%
Other, $12.3 mio, 4%
IOD, $16.4 mio, 6%
OD-F, $91.7 mio, 31%
CCR, $65.5 mio, 22%
DCTD, $66.2 mio, 22%
IOD, $16.4 mio, 6%
OCG $4.4 mio, 2%

CBIIT – Center for Biomedical Informatics and Information Technology
CCR – Center for Cancer Research
DCEG – Div. of Cancer Epidemiology and Genetics
DCTD – Div. of Cancer Treatment and Diagnosis
IOD – Immediate Office of the Director
OCG – Office of Cancer Genomics
OD-F – Office of the Director - Frederick
OD-CSSI – Office of the Director - Center for Strategic Scientific Initiatives
DCTD: The NCI Experimental Therapeutics Program (NExT)

- NExT is led by the Division of Cancer Treatment and Diagnosis to create a coordinated cancer therapeutics discovery and development pipeline with the external scientific community
  - Projects evaluated by extramural Special Emphasis Panel

- FNLCR provides operational and dedicated technical support to all phases of NExT programs

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Small Molecule Repository

- Chemical Biology Consortium
- Molec. Charact. Lab
- Bioph.Dev.Prgm.(BDP)

Clinical Target Valid. Lab

- Clinical Assay Development Program
- BDP Production, Quality Assur.
Established in 1993 to provide specialize expertise and service not available in the commercial market

- More than 100 distinct products have been manufactured
- More than 60 products have entered clinical trials

150 L and 500 L Fermentors
**Concept**: ch14.18 marks neuroblastomas for killing by the immune system by binding to an overexpressed antigen called GD2

- Due to complexity of process and small market, no commercial vendor would make the antibody

Children’s Oncology Group Phase III trial in patients with high-risk neuroblastoma demonstrated clear event-free survival benefit

With the success of the trial, a commercial vendor has been found and our process transferred
• Develop a system to provide accurate and objective monitoring of trials and accruals by NCI-designated Cancer Centers (Coordinating Center for Clinical Trials)

• FNLCR provides project planning and management, software development and quality assurance.

• Built on an enterprise-wide platform that supports the Cancer Therapy Evaluation Program (CTEP), the Division of Cancer Prevention (DCP), ClinicalTrials.gov, credentialing, automated patient-trial matching and the capture of key data elements in emerging clinical trials, such as biomarkers.
• Conduct high quality molecular epidemiology studies of cancers and related traits
• Provide expertise for all aspects of genetic analyses
Evolutionary Dynamics of the Human NADPH Oxidase Genes CYBB, CYBA, NCF2, and NCF4: Functional Implications

Eduardo Tarazona-Santos,1,2,15 Moara Machado,1,2,15 Wagner C.S. Magalhães,2 Renee Chen,1 Fernanda Lyon,1 Laurie Burdett,1,15 Andrew Crenshaw,1,15 Cristina Fabbi,1 Lalita Pereira,1 Laelia Pinto,2 Rodrigo A.F. Redondo,1 Ben Sestanovics,1 Meredith Yeager,15 and Stephen J. Chanock1,15

Original Investigation

The new sequencer on the block: comparison of Life Technology’s Proton sequencer to an Illumina HiSeq for whole-exome sequencing


LETTERS

Meta-analysis identifies four new loci associated with testicular germ cell tumor


LETTERS

Detectable clonal mosaicism and its relationship to aging and cancer


LETTERS

Genome-wide association analysis identifies new lung cancer susceptibility loci in never-smoking women in Asia

Qing Lai1,6, Cho A. Hoang2,4, Keitaro Matsuo3,6, Yun-Chul Hong6,6, Adeline Secou5,6, Zhoming Wang6,6, H. Dean Hoang1,1,4, Kevin Chen6,6, Jun-Can Wang6,6,6,6, Nilsanjan Chatterjee1, Wei Hu1, Maria Pik Wong1,6

Comprehensive resequencing analysis of a 123kb region of chromosome 11q13 associated with prostate cancer

Charles C. Chung1, Joseph Roland1,2, Meredith Yeager1,2, Kevin B. Jacobs1,2, Xinjun Zhang1,2, Zuoming Deng1,2, Casey Matthews1,2, Sonja L. Berndt1, and Stephen J. Chanock1

COMMENTS

Improved imputation of common and uncommon SNPs with a new reference set

“The biomedical research community spends $2 billion per year on antibodies, half of which do not work” *


*Biocompare Surveys and Reports, March 24th, 2009
• Project delivery
  – Management
  – Engineering
  – Controls

• Facilities maintenance
  – ~2 Million ft²
  – 9000 trouble calls / yr

• Facilities operations
  – Custodial Services
  – Special assists
...pivots to **IOD** – Cancer Research Technology Program and RAS

**RAS Program**

**LABS in ATRF**

- CSSI: NCL
- CSSI: ACL
- CCR: SF
- DCEG: Hormone

**Advanced Technology Core Labs**

- Imaging Labs
- EML
- OMAL
- PEL
- LPAT
- PCL
- Genomics

**RAS Labs**

**RAS Services**

**Dedicated**

*Project-based assignment* | Dedicated to RAS

*Project-based assignment as well as Core Services*
Conclusions

- Leidos Biomedical Research, Inc. is owned by Leidos Holdings, Inc., and operates FNLCR for the NCI in the Public Interest

- Most NCI Appropriated funding comes from individual Divisions, Offices, and Centers to support their specific objectives

- FNLCR staff drive NCI program objectives by integrating technical, operational, and contracting expertise