

GOGOS AND GOCOS — SIMILARITIES AND DIFFERENCES: WHAT CAN WE LEARN FROM EACH OTHER?

Courtney Silverthorn, Ph.D.
Intellectual Property Specialist
SAIC-Frederick, Inc.
FLC Mid-Atlantic Meeting – Training
October 4th, 2011

SESSION OBJECTIVES

- Overview of the mission of the National Cancer Institute
- Overview of NCI-Frederick as a Federally Funded Research and Development Center (FFRDC) and as a Government-Owned, Contractor-Operated facility (GOCO)
- SAIC-Frederick's technology transfer mechanisms
 - Economy Act
 - Subcontracts
 - CRADAs
 - Copyright

NATIONAL CANCER INSTITUTE MISSION

- The National Cancer Institute (NCI) is part of the National Institutes of Health (NIH), which is one of 11 agencies that compose the Department of Health and Human Services (HHS)
- Established under the National Cancer Institute Act of 1937 and broadened under the National Cancer Act of 1971, the NCI is the Federal Government's principal agency for cancer research and training.
- Coordinates the National Cancer Program
 - Conducts and supports research and training
 - Health information dissemination
 - Other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and their families

NCI-FREDERICK

- A Government-Owned, Contractor-Operated laboratory
- One of only 40 Federally Funded Research and Development Centers (FFRDC) and the only FFRDC within the Department of Health and Human Services
- SAIC-Frederick, Inc. is the Operations and Technical Support (OTS) contractor for NCI-Frederick
 - Technology and Research Group (ATP, AIDS and Cancer Virus Program, Basic Science Program)
 - Clinical Group (Clinical Research Program, BDP, VCMP)
 - Operations Group (Contracting)

FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS

- “The FFRDC is a special business model defined under government regulations that require the contractor to be autonomous, or a separate operating unit of a parent company, and to operate in the public interest. It also permits special access to privileged government information and facilities, and it allows broad latitude in subcontracting.”
- “Authorities granted to the FFRDC guarantee **flexibility, efficiency, rapid response, and accountability**. This enables the FFRDC to **respond rapidly** to new and emerging mission-critical initiatives of NCI and to **manage public-private partnerships** that accelerate the delivery of new treatments to cancer patients.”

-SAIC-Frederick: About Us webpage

FFRDC FACTS

- Federal Acquisition Regulation Clause 35.017 provides FFRDC policies and procedures
- Meet special long-term research or development need
- Have enhanced access to Government and supplier data, including sensitive and proprietary data, and to employees and installations equipment and real property

FFRDC LIMITATIONS

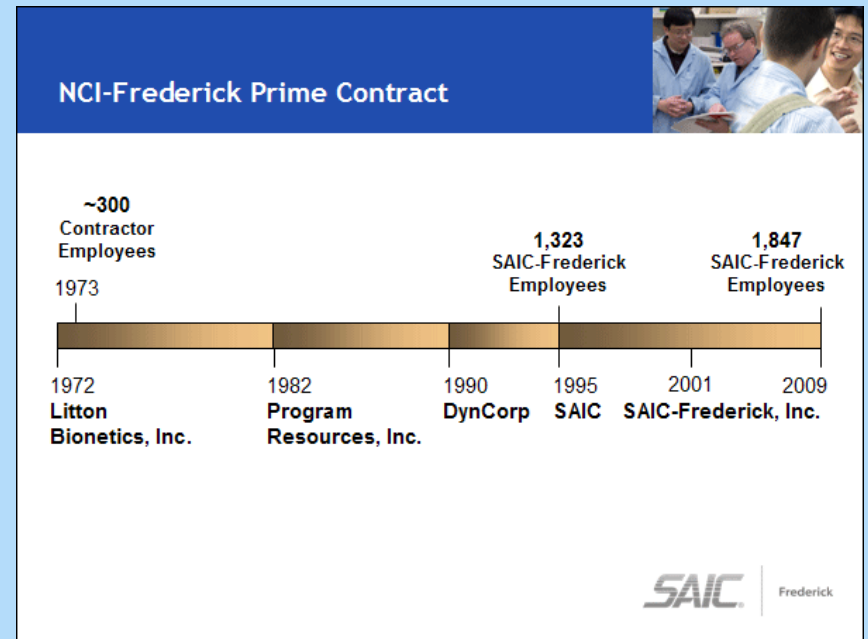
- Due to special relationship between Government and FFRDC, the FFRDCs are limited in other contracting opportunities
- FFRDCs have similar restrictions as federal agencies on receiving funding other than government appropriated funds that come directly through contract
- Must not compete with the private sector

GOVERNMENT-OWNED, CONTRACTOR-OPERATED FACILITIES

- “A GOCO partnership **allows each partner to perform duties for which it is uniquely suited**: the government establishes mission areas, and the private sector implements the missions, using best business practices.”
- “The GOCO allows proven private-sector processes to operate **without bureaucratic restrictions**. Scientists performing for a GOCO contractor are largely **insulated from political pressures**. Thus, they have the independence to speak out as honest brokers, acting truly in the national interest.”
 - Sandia National Laboratories Website

NCI-FREDERICK – A UNIQUE GOCO

- Resources managed by SAIC-Frederick include:
 - Advanced Technology Partnerships Initiative
 - Nanotechnology Characterization Lab
 - Biopharmaceutical Development Program
 - Advanced Biomedical Computing Center
 - Vaccine Pilot Plant



GOCO TOOLS ARE SIMILAR TO GOGO TOOLS

- Federal WFO – 31 U.S.C. § 1535 (the Economy Act) allows GOCOs to work for federal agency sponsors other than their federal agencies, through the Interagency Agreement
- Non-Federal WFO – Dept. of Energy and NASA and their FFRDCs have specific authority to work for non-federal sponsor; DHHS does not
- Subcontracts – A majority of funds received by SAIC-Frederick are further subcontracted out to large and small businesses and academic institutions to support NCI, NIAID, and NHGRI projects
- CRADAs – 15 U.S.C. § 3710a authorizes federal laboratories, including GOCO laboratories, to enter into CRADAs and to receive funds to support CRADA projects
- Copyright – One major distinction between federal agencies and contractors is the ability for contractors to assert copyright

FEDERAL WFO UNDER
THE ECONOMY ACT

THE ECONOMY ACT

- Created as a method to avoid duplication of work on the Government's behalf
- Permits all federal agencies to buy goods and services from one another, rather than only from the private sector
- Utilize Inter-Agency Agreements (IAAs)
- Advantage: Transfer of funding into NCI (or indirectly to SAIC-F) to provide unique goods and/or services for use by another Federal agency
- Disadvantage: A procurement mechanism for use only between Government agencies; thus cannot be used to work with academic institutions or for-profits directly

FEDERAL WFO AT SAIC-FREDERICK

- Nanotechnology Characterization Laboratory
 - NCI-NIST-FDA partnership
 - Accelerate the characterization of nanomaterials for use in cancer imaging, diagnosis and treatment through a standardized characterization cascade
- Proteomics Initiative
 - NCI-DOE partnership (Argonne National Laboratory)
 - Develop tools for analyzing the proteome on a broad scale in order to share them with the larger R&D community

SUBCONTRACTS

BENEFITS OF A CONTRACT TO THE GOVERNMENT

- Work done by the contractor is for the direct benefit of the Government
- R&D Contractor usually performs work “independently and not as an agent of the Government”
- The Government receives tangible items, services, or data from the contractor
- The Government can specify what is to be done by the contractor to specific standards (in the RFP)
- A robust GOCO subcontracting program can result in increased project flexibility, free up government resources, and possibly produce faster results through streamlined procedures

UNIQUE CHALLENGES OF SAIC-FREDERICK

- Federally Funded Research and Development Center
 - Unusually close relationship with government (must avoid personal services)
- The broad, complex and dynamic nature of the support expected of SAIC-Frederick
- Spirit & intent of the Federal Acquisition Regulation
 - Subcontracts are subject to both federal terms and corporate terms
- More generally, increased scrutiny on federally-funded subcontract dollars
- Varying legal or policy considerations
 - Federal Contract and Common Law, FAR, UCC, state laws, SAIC-Frederick & subcontractor's organizational policies
- Who is SAIC-Frederick's customer?
 - From subcontracting perspective we have two: the specific NCI program and the NCI-Frederick's Contracting Officer
 - Often referred to as the "2 NCIs" whose needs can be diametrically opposed

TYPES OF CONTRACTS

- Contracts involving Research, Development or Experimental work are subject to Bayh-Dole
- Other contract types (e.g., service, time and materials) are not necessarily subject to Bayh-Dole unless include R&D or an applicable clause
- Rights in Data Clauses are often found in all types of contracts
- Intellectual Property Clauses can be added to a contract of any type if IP is anticipated

LAW, POLICY AND GUIDANCE

- The Federal Acquisition Regulation (FAR): A collection of pre-approved legal clauses and descriptions of when particular clauses should be used in a Government contract
 - Chapter 27 deals with IP
 - Patent Rights Clause 52.227-11 (or 12-13)
 - Rights in Data Clause 52.227-14 (or 15-23)
- Note that there are also Agency-specific clauses (HHSAR, DFAR, DEAR...)

MINIMIZING THE IMPACT OF IP

- The Statement of Work may be drafted to reduce the likelihood of invention by the contractor (“a directed pair of hands”)
- Make sure everything you want now or in the future is in the Deliverables section
- Use the appropriate FAR clauses for Patent Rights and Rights in Data to achieve Program goals
- Know the benefits and limitations of the FAR clauses that relate to IP

OWNERSHIP VS. ACCESS

Myth: The Government paid for it, so the Government owns it.

Reality: The Government has access to Intellectual Property and data produced under contracts or grants, but NOT necessarily ownership.

FAR CLAUSES – DATA RIGHTS

■ FAR 52.227-14 Rights in Data - General

- Standard data rights clause that is most often used
- Contractor must get Contracting Officer permission to assert copyright (except in scientific and technical articles)
- Govt. has “unlimited rights” including distribution of software IF no assertion of copyright
- Contractor may use data including software first produced under the contract as they wish

■ FAR 52.227-17 Rights in Data - Special Works

- The contractor will assign copyright to the Government when directed to do so by the Contracting Officer
- The contractor may NOT use data including software produced under the contract for its own purposes
- Used only when justified for specific situations/deliverables

FAR CLAUSES – PATENT RIGHTS

- **FAR 52.227-11 Patent Rights - Ownership by the Contractor**
 - Patent Rights to inventions belong to the contractor (per Bayh-Dole)
 - The Government has a license to practice contractor inventions or have them practiced on the Government's behalf
 - The Government retains "march-in rights"
 - The prime contractor must flow-down the IP FAR clause to subcontractors
 - The prime contractor (or its subcontractors) are obligated to report their respective inventions to the Government
 - There are contractor requirements for U.S. manufacture
 - Utilization reporting required
- **FAR 52.227-13 Patent Rights - Ownership by the Govt.**
 - The Government retains title to the contractor's inventions
 - Contractor gets a license to practice the invention
 - Contractor may request Greater Rights to the invention
 - Per NIH Office of General Counsel, application of this clause requires a Determination of Exceptional Circumstances (DEC)

WHAT IS A DEC?

- A Determination of Exceptional Circumstances (DEC) is a document drafted by an Agency to justify the restriction or elimination of the Bayh-Dole rights of those awarded a contract, grant or cooperative agreement
- Typically, NIH will not approve a DEC for grants or cooperative agreements
- A DEC may only apply to a narrowly identified contract or class of contracts
- DEC's do NOT automatically flow down to subcontractors
- Final approval for the DEC is made by the Agency Director after EXTENSIVE review

EXAMPLES OF EXCEPTIONAL CIRCUMSTANCES

- Making certain research tools widely available without IP constraints to the research community (e.g. Full-Length cDNA program, Initiative for Chemical Genetics)
- The NCI-Frederick FFRDC contractor (currently SAIC-Frederick)
- Protection of proprietary third-party materials (e.g. RAID, CRADAs involving the FFRDC contractor, Screening programs)

WHAT CAN THE GOGOS LEARN?

- A GOCO subcontracting program can be an efficient way to implement and manage contracts to the benefit of the government
- Differentiating between access and ownership of new subject inventions and appropriate FAR clauses for each
- DEC's can be extremely useful and appropriate for managing specific programs but are not an easy undertaking

COOPERATIVE RESEARCH
AND DEVELOPMENT
AGREEMENTS

CRADA SUBJECT IP

- Subject invention – any invention that is conceived or first actually reduced to practice in the performance of work under a funding agreement, such as OTS contract or CRADA
- Ownership follows inventorship
- Collaborator is granted an option to negotiate a non-exclusive or exclusive commercial license

SAIC-FREDERICK DEC AND IP

- Determination of Exceptional Circumstances (DEC)
Under Bayh-Dole Act – SAIC-Frederick assigns right and title in intellectual property to the US Government and retains a right to use
- With DEC in place, SAIC-Frederick cannot assign IP to any party other than the Government, as may be required in a CRADA

NCI-FREDERICK CRADAS

- NCI can negotiate CRADAs with a Collaborator on behalf of a SAIC-Frederick investigator
- OTS contract allows SAIC-Frederick to negotiate CRADAs without NCI as a party, but SAIC-Frederick is not currently doing so

CRADAS UNDER OTS CONTRACT

- The OTS Contract Article H.16. Technology Transfer states that “technology transfer (including CRADAs) is established as a mission of the Laboratory ...”
- NCI-Frederick is in the process of implementing a Contractor CRADA process
 - Amending the DEC
 - Amending the contract
 - Implementing standard processes and templates

NCI APPROVAL OF SAIC-FREDERICK CRADA

- SAIC-Frederick's CRADA approval process is being modeled on Dept. of Energy process
- SAIC-Frederick IP department will negotiate the CRADA using one of two pre-approved templates
- Substantial modifications to CRADA model will have to be approved by NCI-Frederick

SAIC-FREDERICK CRADA USES

- Used as an alternative to a Material Transfer Agreement (MTA) if outside party requires promise of rights to subject inventions (M-CRADA model)
- Used as an alternative to non-federal WFO to fund a specific project being carried out only by SAIC-Frederick investigators (S-CRADA model)
- Support for SBIR/STTR activities, particularly for collaborations anticipated in the Riverside Research Park

WFO VERSUS CRADA

WFO	CRADA
Service	Collaboration
Outside party pays 100% of project cost	Collaborator funds all, some or none of project; must provide something, e.g. materials or expertise, other than funding
Lab service must be unique	Collaborator should be unique OR lab has to show why Collaborator was chosen OR advertise opportunity for partnering
Lab must not compete with public sector	Lab must provide fair access
NCI/SAIC-Frederick DO NOT have authority	NCI/SAIC-Frederick DO have authority

CRADA FUNDING

- Researchers are often the first contact with outside party and may be reluctant to discuss funding
- No standard formula to determine how much other party funds. Factors include: NCI/SAIC-Frederick's interest in project, ability of other party to pay, program funding, other contributions such as materials, expertise

CRADA FUNDING

- OTS Contract Article H.16.a(8) Technology Transfer, Disposition of Funds – tracking and reporting requirements
- Article H.16.a(8)(a) – any funds received under a CRADA shall be reported to Contracting Officer within 30 days. For each CRADA, must maintain a separate cost center itemizing costs expended
- Article H.16.a(8)(b) – within 30 days of end of each contract year SAIC-Frederick shall provide to Contracting Officer a separate accounting of how CRADA funds were expended

WHAT CAN THE GOGOS LEARN?

- Awareness of how agency IP policies (including any relevant DECAs) affect collaboration opportunities of your GOCO
- A properly structured CRADA can enable many different kinds of collaborative projects, absent other specific authorities

COPYRIGHT AND SOFTWARE

COPYRIGHT

- US Government does not assert copyright in works created under official duties of employees
- Contractors can and do assert copyright – particularly relevant to software
- Contractors can assign copyright to another entity (i.e. a publisher) or the government

COPYRIGHT AND PUBLICATIONS

- Ability to hold copyright in scientific publications affects journal submission process
- NCI uses the NIH Publishing Agreement
- SAIC-Frederick has developed a similar agreement for use by employees

COPYRIGHT AND SOFTWARE

- NIH treats software as any other reportable invention
 - 99.99999...% of the time – designated as Research Tool and distributed under various software agreements
- Other agencies may have commitments to open-source software and disseminate freely
- GOCOs could copyright software source code, either under their own initiative or at the request of the government

MANY THANKS TO

- Dr. Jeff Thomas, Frederick Unit Supervisor, NCI Technology Transfer Center
- Marianne Lynch, IP Attorney, SAIC-Frederick
- Shannon Jackson, Prime Contract Manager, SAIC-Frederick

Contact Information:
Courtney Silverthorn, Ph.D.
silverthorncf@mail.nih.gov
301-846-6316

THANK
YOU!

Questions
and
discussion?