Maximizing U.S. Returns on Shared Knowledge: Innovative Frameworks for Technology Transfer and Full Global Engagement

Government-University Industry Research Roundtable (GUIRR) Meeting – June 3, 2009

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Sharing Knowledge, Sharing Progress, Sharing Benefits:
Working Together in Harmony

Presented 2009 June 03 at GUIRR by:

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National Institutes of Health (NIH)

NIH is an Agency of the
U.S. Department of Health & Human Services (HHS)

NIH Mission:

Science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.

NIH-Supported Research

NIH supports research in the U.S. and with international collaborators, and internationally.
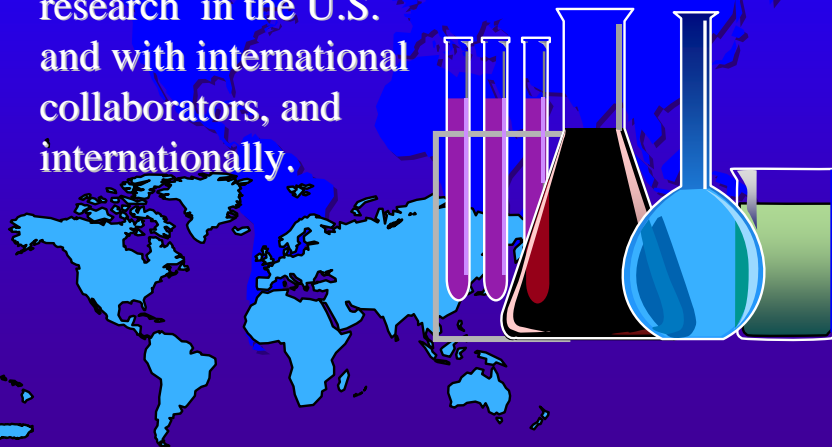
Dual Nature of NIH Supported Research

INTRAMURAL

EXTRAMURAL

Office of Extramural Research (OER)
Office of Intramural Research (OIR)

NIH – Intramural & Extramural

NIH INTRAMURAL RESEARCH
NIH is an Institution

Supports:
- Over 6,000 scientists
- 10% of NIH budget
- Primary location: Bethesda, MD
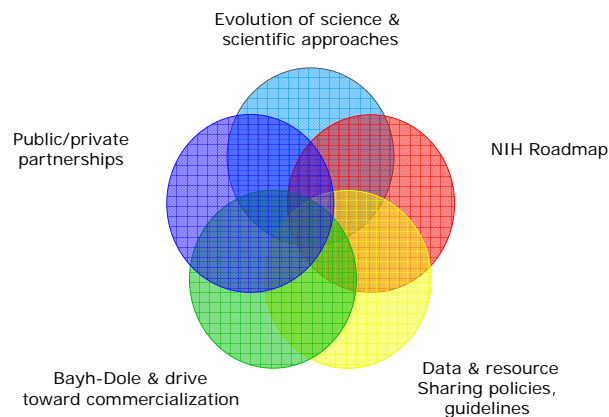- A few other labs throughout the United States (U.S.)

NIH EXTRAMURAL RESEARCH

FY 2005 NIH Extramural Grants by Research Institution

Supports:
- Over 3,000 Institutions worldwide
- Over 300,000 scientists & research personnel
- Awards issued to over 100 countries
- Clinical, Basic, & Translational Research
- 83% of the NIH budget

The sharing environment is complex and rapidly evolving…

- Evolution of science & scientific approaches
- Public/private partnerships
- NIH Roadmap
- Bayh-Dole & drive toward commercialization
- Data & resource Sharing policies, guidelines

NIH – A Longstanding History of Sharing in Progress

Public Health Service (PHS) Grants Policy Statement (pre-1980)

"Project directors and principal investigators are encouraged to make the results and accomplishments of their activities available to the public."

NIH – A Longstanding History of Sharing in Progress

PHS Grants Policy Statement - Pre-1980
NIH Guide Supplement - 1980 – Hybridoma Sharing
NIH Guide Notices - 1984, 1986, 1987, 1988 – Sharing of Unique Biological Materials
PHS Grants Policy Statement - 1990 – Sharing of Unique Research Resources
Developing Sponsored Research Agreements – 1994
Biological Materials Policy - 1996
NIH Intramural Research Program Guidelines for the Availability of Transgenic/Knockout Animals – 1997
NIH Research Tools Policy - 1999
    NIH Data Sharing Policy – 2003
NIH Model Organism Sharing Policy – 2004
NIH Public Access Policy – 2005 (Revised 2008)

NIH – A Longstanding History of Sharing in Progress

NIH Sharing Policies Website and Email:

NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources (http://sharing.nih.gov)

Email: Sharing@nih.gov

Sharing – Benefits and Challenges

Examples of Benefits:
- reinforcing open scientific inquiry
- encouraging diversity of analysis and opinion
- promoting new research, testing of new or alternative hypotheses and methods of analysis
- supporting studies on data collection methods and measurement
- facilitating education of new researchers
- enabling the exploration of topics not envisioned by the initial investigators
- permitting the creation of new datasets by combining data from multiple sources

Sharing – Benefits and Challenges

Examples of Benefits (continued):
 - economic efficiencies and synergy in research (e.g., funding
 non-duplicative research efforts)
 -scientific reputation grows
 -scientific validity (e.g., reproducible and comparable results)

Sharing – Benefits and Challenges

Examples of Challenges and Concerns:
 - Accessibility
 - Usable, Sharable, and Meaningful
 - Confidentiality
 - Informed Consent
 - Privacy
 - Intellectual Property
 - Domestic and international levels

Challenges of Standardization and Harmonization

"Singing from the Same Sheet of Music" – Working together

- Standardization
    - Everyone singing the same Melody line together
    - A simpler approach, only need to learn one thing
    - A louder unified sound by the players (no real soloists)

Challenges of Standardization and Harmonization

Examples of Standardization Efforts:
- The Metric System
    - an internationally decimalized system of units for measurement
    - Some exceptions include United States, Myanmar, Liberia, United Kingdom, and Hong Kong.
    - The US Metric Conversion Act in 1975 and the Omnibus Trade and Competitiveness Act of 1988 encouraged U.S. industrial metrication.
    - No deadline for conversion
- Esperanto
    - A language developed to foster harmony between people from different countries

Challenges of Standardization and Harmonization

"Singing from the Same Sheet of Music" – Working together

-Harmonization
- Each person singing their different part of the score together
- More complex, each must learn their part, and requires coordination among players
- A richer, layered, nuanced, and coordinated sound by the players working together
- "Balance" in volume achieved by assigning and moderating parts (e.g., may have soloists)
- Requires a coordinator or leader

Which is better for working together?

Challenges of Standardization and Harmonization

Complexity of Varying Laws, Regulations, and Policies in the Domestic and International Environments

- Domestic Environment and Federalism
- Balancing and sharing of governing power between national and local authorities
- Federal and States may pass laws covering same activity in certain overlapping areas of authority
- A state law can be consistent with a federal law while being more narrow and specific (so not "standardized" across the states)
- Pre-emption
-A valid federal law or federal regulation takes precedence over a conflicting state law or state regulation for the same activity
- State sovereignty
- Example: State laws may differ on ownership of samples

Challenges of Standardization and Harmonization

Complexity of Varying Laws, Regulations, and Policies in the Domestic and International Environments

-International Environment
- International laws, regulations, rules, and policies
- Different authorities and jurisdictions at national and local levels of each country
- Cultural issues
- National sovereignty issues

Challenges for Government-Supported Research

Sharing of Data and other Resources for Research Purposes
  Broader issues
- Standardization/Harmonization of repositories
- Formats, data fields, data structures - same or different
- Collection and Accessibility (who, what, where, when, and how)
    - Example: dbGaP and Data Access Committees (http://gwas.nih.gov)
- Ownership of data and samples and related proprietary and intellectual property issues (e.g., reach throughs and returns)
- Publication
- Standardizing transfer agreements (e.g., SLA, UBMTA)

Challenges for Government-Supported Research

Sharing of Data and other Resources for Research Purposes
- Internationally
    - Differences in various legal systems
        - how to regulate privacy under different legal systems
        - informed consent
        - ownership of data and materials
    - Differences in cultural perspectives

Challenges for Government-Supported Research

Access and sharing of research materials
    - Indonesian and Avian Flu
        - Flu sample access issues
        - Maintaining sovereignty over property within its borders and possession, and cultural understanding
            - Pancasila – the 5 intertwined principles governing the philosophy of Indonesia and its culture
            - "Social justice for the whole of the people of Indonesia"
            - equitable spread of welfare to the entire population, all the country's natural resources and national potentials should be utilized for the greatest possible good and happiness of the people. Social justice implies protection of the weak and should prevent willful treatment by the strong and ensure the rule of justice.
            - Sharing in the benefits (e.g., vaccines)

Challenges for Government-Supported Research

Export Controls

- U.S. Department of Commerce's Bureau of Industry and Security (BIS)
    - Deemed Export Advisory Committee's (DEAC) report of 2007
    - A "deemed export" is the transfer of sensitive dual-use technology to a foreign national working or studying in the United States.
    - Foreign nationals play a significant role in the U.S. research system, so deemed export policy has significant implications for U.S. national security and economic competitiveness.
    - U.S. rules should not permit the transfer of sensitive U.S. technology to a real or potential adversary, but these rules must ensure the United States remains the most innovative and competitive economy in the world.

Challenges for Government-Supported Research

Export Controls

- Deemed Export Advisory Committee's (DEAC) Report of 2007
    - Actively Evaluating Commerce Control List (CCL) Subject to Deemed Export Licensing
        - NIH supports (i) identifying emerging technologies that should be added or remain on the CCL because they form a direct threat to and affect national security; and (ii) removing technologies from the CCL that no longer directly affect and threaten national security and are readily available outside of the U.S.
    - Comprehensive Assessment of Foreign National Affiliations
        - Foreign nationals engaged in NIH supported research
        - Visa Mantis security review is exhaustive and comprehensive, so further review should be based on credible and specific information of a threat

Challenges for Government-Supported Research

National Science Advisory Board for Biosecurity (NSABB)
- Working Group on Personnel Reliability
- Insider threat as to domestic or foreign national
- Draft report with findings and recommendations
- Vision: Personnel approved for access to select agents and toxins are behaving in a responsible and trustworthy manner that upholds public health and safety, national security, and the integrity of the scientific enterprise
- Oversight must balance the need for security with the need for continued scientific progress
- Degree of oversight should be consistent with the likelihood and possible consequences of misuse of select agents and the anticipated effectiveness of a program

Challenges for Government-Supported Research

NSABB Personnel Reliability Report (2009-05-20)
Recommendations:

1. It is appropriate to enhance personnel reliability measures for individuals with access to select agents, but the promulgation of a formal, national Personnel Reliability Program is unnecessary at this time.

2. The current SRA (Security Risk Assessment) process should be strengthened.

3. The culture of responsibility and accountability should be enhanced at institutions that conduct select agent research.

Challenges for Government-Supported Research

NSABB Personnel Reliability Report (2009-05-20)
Recommendations (Continued):

4. Professional societies should continue to encourage an ongoing dialogue about personnel reliability to maintain vigilance about biosecurity issues throughout the research community and to foster community-based solutions.

5. The List of Select Agents and Toxins should be reduced or stratified.

Recipients of NIH Funding

- U.S. laws, regulations, rules, and policies apply to NIH-funding awards to both domestic and international funding recipients.

Financial Conflict of Interest (FCOI) Regulations

- 42 CFR Part 50 Subpart F (grants and cooperative agreements)

- 45 CFR Part 94 (contracts)

  These regulations went into effect on October 1, 1995

What is the Purpose of the Regulation?

- This regulation is aimed at ensuring that the design, conduct, or reporting of research funded under NIH grants and cooperative agreements will not be biased by any conflicting financial interest of the Investigators responsible for the research.

Who is covered?

- Each Institution that applies for NIH grants or cooperative agreements for research
    - Domestic, foreign, public, private (not Federal)
- Any Investigator, as defined by the regulation, participating in the research
- SBIR/STTR Phase I applications are exempt

What is an FCOI?

- A significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH funded research

Institutional Responsibilities

Institutions must establish standards to ensure there is no reasonable expectation that the design, conduct, or reporting of NIH funded research is biased by a conflicting financial interest of an Investigator

Advanced Notice of Proposed Rulemaking (ANPRM)

- NIH Requests Comments on Proposed Amendment of Regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors" - NIH Guide – NOT-OD-09-099 published May 8, 2009.
    - http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-099.html

- Federal Register (Vol. 74, No. 88) May 8, 2009

- 60-day comment period – closes July 7, 2009

- Comments accepted in Regulations.gov, by mail, fax or hand delivery (comments may not be submitted by email). See NIH Guide Notice for details.

- Could subsequently lead to NPRM and a new Final Rule

Advanced Notice of Proposed Rulemaking (ANPRM)

- Addresses various topics including:
  - Expanding the scope of regulation and disclosure of interests;
  - Definition of "Significant Financial Interest";
  - Identification and management of conflicting interests by institutions;
  - Assuring institutional compliance;
  - Requiring institutions to provide additional information;
  - Broadening the regulations to address institutional conflict of interest
- Programmatic Inquiries only
  - Email: FCOI-ANPRM@NIH.GOV
  - Note: No comments may be submitted by email.

Summary

- U.S. laws, regulations, rules, and policies apply to NIH funding awards to domestic and international NIH-funding recipients.

- Sharing knowledge and working together cooperatively promotes a synergy and moves research forward efficiently and effectively, thus helping to achieve public health benefits for the global community. Standardization and harmonization efforts emphasize working together to achieve these goals.

- U.S. rules must ensure the United States remains the most innovative and competitive economy in the world, but should not permit the transfer of sensitive U.S. technology to a real or potential adversary.

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