



RESEARCH TOOLS: THE NIH POLICY AND PRACTICES

SURY VEPA, Ph.D., J.D.

Licensing and Patenting Manager
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health
U.S. Department of Health & Human Services

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Outline of Today's Discussion

- Introduction
- Rationale and Content of NIH Research Tool Guidelines
- NIH Patenting and Licensing Practices for Research Tools
- Examples of Successful Research Tool Transfers
- Summary



Research Tools: Lifeblood of Basic Research

- “Targets” and “Tools” for discovery
- Wide variety of resource types:
antibodies, receptors, animal models, libraries, software and databases
- Broad access & availability needed
- Readily useable & distributable
- Useful lifecycle generally short



Examples of Research Tools

- D2 dopamine receptor screening tool
- immortalized liver cells disease model
- “knock-out” mice disease model
- basement membrane reagent sales
- multi-drug resistant cells screening tool
- HIV protease screening tool





Rationale for Developing NIH Research Tools Policy

Past:

- Historical culture and practice of unrestricted flow of materials

What happened:

- Increased Commercial uses for molecular biology tools
- Universities & Federal labs obtain ownership rights to invention
- Pharma MTA/licensing practices adopted

The Result:

- Lengthy negotiations and undue restrictions
- *Increased unavailability of research resources*
- *Concerns from stakeholders*

Findings of NIH Advisory Group:

- Research tools have value as a commodity
- Need to recognize the contribution of inventors
- Public health benefit still paramount




The NIH Research Tools Policy

- **Principles:**
 - ensuring academic freedom and publication
 - minimizing administrative impediments
 - implementing Bayh-Dole Act
 - disseminating research resources
- **Guidelines:** specific information, strategies & model language for Recipients in obtaining and disseminating resources

“Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts”


December 23, 1999

www.ott.od.nih.gov/pdfs/64FR72090.pdf




Principle 1: Ensure Academic Freedom & Publication

- Preserve academic research freedom
- Safeguard appropriate authorship
- Timely disclosure of results
- Applies to *all* funding recipients



Principle 2: Ensure Appropriate Implementation of Bayh-Dole Act

- Maximize utilization by research community
- Timely transfer to industry for commercialization
- Patent protection not always needed
- License to ensure widespread distribution of products to public
- Avoid unnecessarily restrictive licensing practices



Principle 3: Minimize Administrative Impediments To Research

- Streamline academic transfers using Simple Letter Agreement (or equivalent)
- Implement clear tool acquisition policies
- Avoid encumbrances such as:
 - “reach through” or product rights
 - publication / academic freedom control
 - improper valuations



Principle 4: Ensure Dissemination of NIH-Funded Tools

- Determine if you have a research tool
 - for discovery - not a FDA-approvable product
 - broad, enabling or with many uses
 - readily useable or distributable
- Widespread, timely distribution necessary
- Simple Letter Agreement to non-profits
- Share distribution principles with non-NIH research co-sponsors
- Simplify transfer to for-profits for internal use
- Limit exclusive licenses to appropriate fields of use
- Retain tool use & distribution rights



NIH Patenting Policy

Do not seek patent protection if:

- Commercialization and technology transfer can best be accomplished without patent protection
- further research and development is **not necessary** to realize the technology's primary use



Seek patent protection if:

- facilitates availability of the technology for preventive, diagnostic, therapeutic, or other commercial use
- further research and development is necessary to realize the technology's primary use
- commercial or public health value of the technology warrants the expenditure of funds
- research has a practical utility or a reasonable expectation of future practical utility



NIH Licensing Principles

- Grant only the appropriate scope of rights
- Permit research uses
- Preference for non- or partial exclusivity
- Specified fields of use
- Enforceable milestones and benchmarks
- Maximize development of products for the public health
- Ensure appropriate return on public investment



Transfer of NIH Research Tools To Academic/Nonprofit Institutions

- Transfers to academic/nonprofit institutions:
 - Simple Letter Agreement (SLA)
 - Model organisms: the MTA-TO
 - Uniform Biological Material Transfer Agreement (UBMTA)
 - Repositories



Transfer of NIH Research Tools To Commercial Parties

- *Biological Materials License Agreement (Internal Use):*

A nonexclusive license that facilitates the internal commercial use of unpatented NIH biological materials.

- *Biological Materials License Agreement (Commercial):*

A nonexclusive license for sale of research tools to others.



Research Tool Licenses from the NIH

- *Research Tool licenses negotiated through the NIH carry no grant-backs or reach-through rights.*
- *IP derived from discoveries made with NIH-licensed tools will remain clear and unencumbered.*

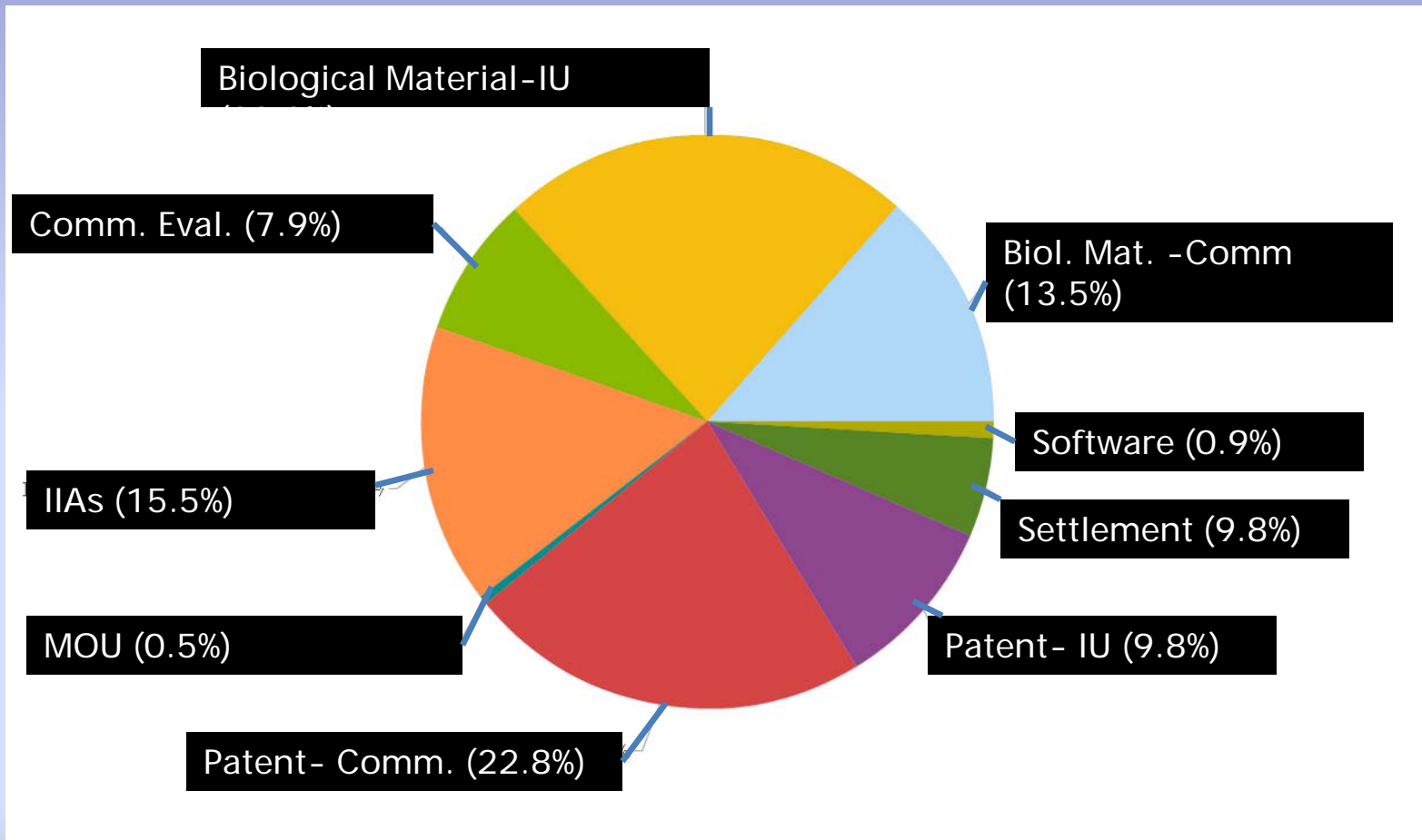
Ben-Menachem, G., Ferguson, S.M., and Balakrishnan, K., “Doing Business with the NIH,” *NATURE BIOTECHNOLOGY*, Vol. 24, no. 1, Jan. 2006

Research Tools Are Important Part of NIH Discoveries





Licenses in FY09 by Type of Agreement





Examples of Successful NIH Research Tool Transfers






BRB Array Tools (Software)

- The invention is a desktop software package that integrates into Microsoft Excel as an add-in for the analysis of DNA microarray data.
- Developed by Dr. Richard Simon and Colleagues at NCI.
- The software incorporates numerous statistical analysis methods tailored to the analysis of DNA microarray data, providing a robust visualization capability for translating the data into biological knowledge that is lacking in currently available packages.
- Licensed to more than 20 for-profit organizations for Internal Use.





BCL-2 Hybridomas (Monoclonal Antibodies)

- The BCL-2 family of proteins plays an important part in apoptosis regulation by either promoting cell survival or inducing cell death.
- Developed by Dr. Richard Youle and Colleagues at NINDS.
- BCL-2 exists as three human isoforms, where the monoclonal antibodies generated are specific for variant I, which plays a role in inducing cell death.
- As a result of BCL-2's unique role as a cell regulator, it is a therapeutic target to promote cell survival in proliferative diseases such as cancer.
- Licensed to more than 20 for-profit organizations for Commercial Sales.



Human Mast Cell Line LAD2 (Cell Line)

- Developed by Dr. Kirshenbaum and Colleagues at NIAID. These mast cell lines closely resemble normal *in vivo* and *in vitro* human mast cells.
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- These cell lines are useful in the development of drugs to treat allergic inflammation.
- The cell line has become the gold standard for allergy and inflammation studies.
- Licensed to over 40 for-profit entities for internal use.
- A patent application filed but was abandoned.



Cell Line Bank for Cancer Research

- This technology describes approximately 439 human tumor cell lines that have important application as research tools to study a wide variety of cancers.
- The cell line bank is the result of exhaustive efforts by NCI scientists.
- Numerous etiologic lung cancer genes were either discovered or validated using these tumor cell lines.
- The technology was distributed to for-profit entities through 17 Biological Material Licenses. Four Commercial Evaluation Licenses were used to grant the nonexclusive right to evaluate the technology's commercial potential. Additional licenses are currently being negotiated.



Summary

- In majority of cases it is possible to promote dissemination and use of Research Tools without the need for patenting.
- NIH OTT has successfully developed and implemented licensing practices that are consistent with the goals of NIH policies on Research Tools.
- *Patents: Not an End in and of Themselves. Depending on the nature of a discovery or invention, technology transfer objectives can be achieved effectively without the need for patenting.*



For Additional Information

- NIH
<http://www.nih.gov>
- NIH Office of Technology Transfer -
<http://www.ott.nih.gov/index.aspx>
- Research Tool Guidelines
http://www.ott.nih.gov/policy/research_tool.aspx
- Best Practices for Genomic Inventions
http://www.ott.nih.gov/policy/lic_gen.aspx
- Model Organisms
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>
- Research Tool Web -
<http://www.research-tool.info/>

