

# Influence of Federal Policy on University Technology Transfer

## Case of the NIH Research Tools Policy

Ansalan E. Stewart, Ph.D.  
Office of Technology Transfer, NIH, HHS  
FLC Mid-Atlantic Regional Meeting  
September 14-16<sup>th</sup>, 2004



# Objectives

---

- Introduce Policy
- Review motivating factors for policy
- Discuss policy
- Summarize influence of policy on university practices

# Research Tools Policy

---

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

[ott.od.nih.gov/NewPages/RTguide\\_final.html](http://ott.od.nih.gov/NewPages/RTguide_final.html)

# What are research tools?

- A resource with primary usefulness for scientific discovery vs. an FDA-approved product or integral component of such a product
- Examples - mabs, receptors, animal models, libraries, computer software and databases
- Broad access & availability needed
- Readily useable & distributable as a tool
- Useful lifecycle generally short
- Patented or unpatented

# Background

Incentive for Policy Development

# Why a need for a policy?

- Scientists experiencing problems related to the dissemination and use of unique research resources.
- Need to balance the competing interests of intellectual property owners and research tools users to address

# Response to a Need

- 1997, NIH Director requested that a Working Group of the Advisory Committee to the Director look into the problems
- Working Group recommended the NIH issue guidance to funding recipients to ensure broad dissemination of research tools while protecting proprietary interests and incentives for commercial development

# Recommendations

- Promote free dissemination of research tools without legal entanglements
- Further use of UBMTA
- Develop guidelines for extramural MTAs and licensing
- Review and strengthen current policies
- Establish “research tools forum”

# Policy Development

- Reviewed NIH's longstanding policy on the sharing of unique research resources
- Reviewed NIH's Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts
- Developed policy based on earlier documents and discussions
- Requested additional comments from industry, academia, and others

# NIH Research Tools Policy

## An In Depth Look

# What is the policy?

- Principles
  - ensuring academic freedom and publication
  - minimizing administrative impediments
  - implementing Bayh-Dole Act
  - disseminating research resources
- Guidelines - Provide specific information, strategies, and model language for Recipient Institutions in obtaining and disseminating biomedical resources

# Principle 1:

## *ENSURE ACADEMIC FREEDOM AND 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 final tool product 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 RESEARCH RESOURCES DEVELOPED WITH NIH FUNDS*

- 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

## Principle 4 (continued):

---

- 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

# Current Status of Policy

- NIH Research Tools Policy adopted for NIH funded research December 23, 1999
- NIH Grants Policy included the NIH Research Tools Policy as an amplification of NIH's longstanding policy of sharing of unique research resources
- Bayh-Dole amended November 1, 2000 to promote its goals “without unduly encumbering future research and discovery” in the spirit of the NIH Research Tools Policy

# NIH Research Tools Policy Influence on University Practices

# Cooperative Field Visits\*

## Purpose:

- Visit Universities to see how the Research Tools is being implemented
- Respond to concerns about the distribution and use of research tools
- Provide guidance to resolve issues associated with implementation of the NIH Research Tools Policy

\* Supplements the guidance we provide via phone and at conferences

# Findings

- University policies and practices are in line with those outlined by the NIH Research Tools Policy
- Majority of universities visited are using principles and guidelines to educate other components of the university e.g. sponsored research staff, contracts staff and faculty
- The guidelines have been used in negotiations to acquire and supply research materials
- Material transfers between universities have been streamlined

## Finding (Continued)

- Acquiring proprietary materials from certain companies are still problematic, yet being able to point to the research tools policy as being a term and condition of their grant funding has enable the universities to avoid signing agreements with egregious terms.
- NIH program staff have been able to use the policy as leverage to motivate researchers to share materials among themselves

# Contact Information

Ansalan Stewart, Ph.D.  
Technology Transfer Policy Specialist  
NIH Office of Technology Transfer  
6011 Executive Boulevard, Suite 325  
Rockville, Maryland 20852-3804 USA  
Telephone: (301) 435-5146  
Fax: (301) 402-0220  
Stewart@od.nih.gov