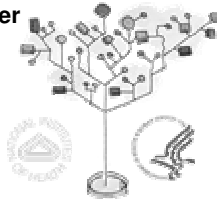


Research Tools Policy and Guidelines and Material Transfer Agreements

Uri Reichman, Ph.D, MBA
Branch Chief
Office of Technology Transfer
National Institutes of Health
U.S. Department of Health & Human Services



India
February , 2006

Research Tools Policy and Guidelines - Background

PRINCIPLES AND GUIDELINES FOR RECIPIENTS OF NIH RESEARCH GRANTS AND CONTRACTS ON OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Purpose:

- To assist recipients of federal funding in complying with their obligations under the Bayh-Dole Act and NIH funding policy
- To facilitate the exchanges of research tools for research discoveries and product development

Policies stemming from Bayh-Dole Act - Research Tools Policy and Guidelines

What happened before 1997

- Problems arised due to lengthy negotiations and undue restrictions
- Increased unavailability of research resources
- Scientific research community raised concerns

Research Tools Policy and Guidelines

HISTORY:

- 1997.....Harold Varmus, NIH Director, establishes a working group to resolve raised issues
- May 25, 1999.....NIH proposal published in FR
- August 1999...All public comments received
- December 1999.....Final Policy and Guidelines in FR

Research Tools Policy and Guidelines

- 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

Research Tools Policy

Principle 1: Ensure Academic Freedom & Publication

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

Research Tools Policy

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

Research Tools Policy

Principle 3: Minimize Administrative Impediments To Research

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

Research Tools Policy

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

Research Tools Policy

Principle 4: Ensure Dissemination of NIH-Funded Tools (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

Research Tools Guidelines

Examples of Research tools:

Monoclonal antibodies
Cell receptors
Cell lines
Knockout mice
Plasmids
Bioinformatics/Software

Research Tools Guidelines

Examples of Research tools:

<u>Tool</u>	<u>Use</u>
• D2 dopamine receptor	screening
• immortalized liver cells	disease model
• ERKO mice	screening
• basement membrane	reagent sales
• MDR cell lines	screening
• HIV protease	screening

Research Tools Guidelines

Research license clause:

“Research License” means a nontransferable, nonexclusive license to make and to use for purposes of research and not for purposes of commercial manufacture, distribution, or provision of services.....

Licensor reserves the right to grant such nonexclusive Research Licenses directly or to require Licenses on reasonable terms. The purpose of this Research License is to encourage basic research, whether conducted at an academic or corporate facility.

Research Tools Guidelines

Ensuring consistent obligations:

NIH Recipients must ensure that obligations to other sources of funding of projects in which NIH funds are used are consistent with the Bayh-Dole Act and NIH funding requirements

Research Tools Guidelines

Guidelines for acquiring Research resources for use in NIH-funded research:

- Avoid restrictions on new tool distribution
- Publication delays (>60 days) unacceptable
- Ownership of recipient's improvements resides with recipient (not provider)

Research Tools Guidelines

Guidelines for acquiring research resources for use in NIH-funded research:

Example language in MTA:

“The project covered by this agreement is supported with funding from the NIH. Provider agrees that after publication, unpatented unique research resources arising out of this project may be freely distributed”

Research Tools Guidelines

Material Transfer Agreements:

MTA
Simplified MTA
SLA

- Material not for use in human
- Material for internal use and not for sale
- Not distributed to third parties without provider's consent
- Recipient to acknowledge provider in publications
- Provider does not provide representations or warranties
- Indemnification
- Recipient to comply with all applicable statutes and regulations
- Confidentiality obligation

Research Tools Guidelines

Vehicles for Material Transfer:

- NIH to not-for-profit organization – at no cost (MTA)
- NIH to for-profit – cost involved (BMLA)
 - Classified as License Agreement
- Material-CRADA (M-CRADA)
 - usually materials transferred to NIH
 - to be used only in pursuit of the CRADA Research Plan
 - Reporting to collaborators on inventions
 - Option to license future inventions by collaborator
 - Reservation of Rights to Use by the Government
- Simplified MTA
 - Informal collaborations
 - Can be done directly by the scientists

Research Tools Policy and Guidelines

- **NIH Director's Forum -**
nih.gov/welcome/forum/
- **Working Group Report -**
nih.gov/news/researchtools/index.htm
- **Research Tool Guidelines -**
ott.od.nih.gov/NewPages/pubs.html
- **NIH Office of Technology Transfer -**
ott.od.nih.gov & NIHOTT@od.nih.gov