NIH Genomic Invention Policies

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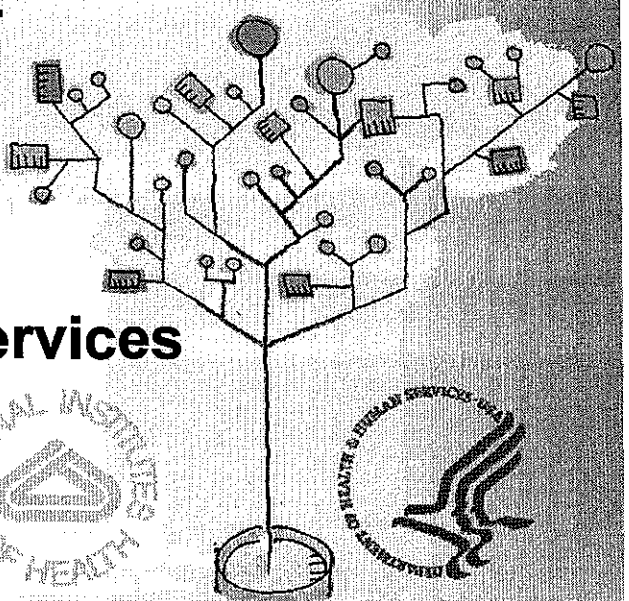


AUTM 2008

National Institutes of Health

Basic Biomedical Research in Support of the Public Health

Funding

Training

Basic → Clinical Research

Inventions

Policies

POLICIES

NIH

- Sharing Biomedical Research Resources,1999
- Sharing Research Data, 2003
- Best Practices for Licensing Genomic Inventions, 2005

OECD

- Guidelines for the Licensing of Genetic Inventions, 2006

Research Tools: The Principles

- Academic Freedom and Publication
- Appropriate Implementation of Bayh-Dole
- Broad dissemination of NIH-funded tools
- Minimizing Impediments to the Research Enterprise

Best Practices for Licensing Genomic Inventions

- If significant R&D is not needed, consider NOT patenting
- If patenting, consider a non-exclusive licensing strategy
- If exclusively licensed, then limit scope, ensure expeditious development, address public health needs

Genomic Science Projects

- Human Genome Project
- International HapMap Consortium
- National Center for Biotechnology Information (NCBI)-NIH
  - GenBank, dbEST, dbSNP, dbMHC
- Genomic Wide Association Studies (GWAS)
- Genetic Association Information Network (GAIN) - dbGaP

GWAS Policy

- Identify common genetic factors that influence health and disease
- Make genotype/phenotype datasets widely available as rapidly as possible
- Deposit data in GWAS repository
- Sharing plan considered in award

GAIN

- PPP between NIH and private sector
- GWAS studies (2000 participants for assay of 300,000-500,000 SNPs)
- Pre-Competitive
- Publish project datasets with pre-computed calculations r^2

GAIN Policy

- IP Policy Requesting access
  - Avoiding making IP claims on data
  - GAIN supported data and conclusions should be freely available
  - Recognize IP appropriate on downstream discoveries
- No publication of data for 9 months from availability of dataset

NIH Product Licensing Principles

- Granting only the appropriate scope of rights
- Reserve right to grant research use licenses
- Refrain from asserting IP against non-profit research
- Preference for non- or partial exclusivity
- Specified fields of use
- Enforceable milestones and benchmarks
- Maximize public health interests (products, uses)
- Ensure appropriate return on public investment

NIH Genomic Invention Licensing

- Distinguish Dx from drug/vaccine product formats
- For Dx, most often non-exclusive licensing
- Higher level of justification for exclusivity than for typical product development
- Permit multiple points of testing and laboratory developed tests, e.g. confirmatory testing by clinical reference labs

Exclusive Licensing of Genomic Dx

- Considered for products regulated by FDA
  - Clinical diagnostics
  - Analyte Specific Reagents
- Provide incentive for development of new products to meet patients' unmet needs for Dx, e.g. rare diseases
- Narrow field of use
- Reserve right to grant non-exclusive licenses for internal and research uses
- Statutory 60 day public notice for comments

NIH Contacts

NIH www.nih.gov

OTT www.ott.nih.gov

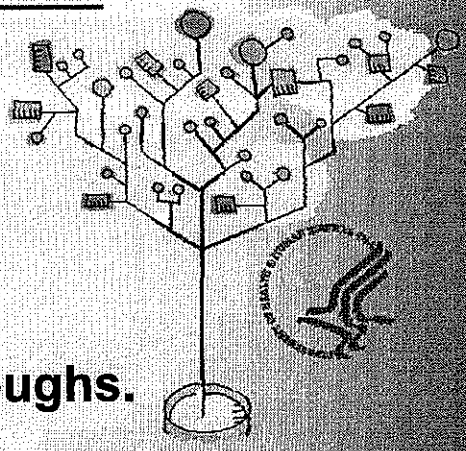
Best Practices

www.ott.nih.gov/policy/lic_gen.html

GWAS

http://grants.nih.gov/grants/gwas/

GAIN http://www.fnih.org



Science. Ideas. Breakthroughs.

Perspective on Gene Patents from the Academic Medical Center

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