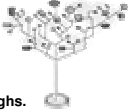


## Role of Technology Transfer Office: The NIH Experience

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Technology Transfer Workshops & Symposium  
Indo-US Science & Technology Forum  
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**Science. Ideas. Breakthroughs.**

## NIH Office of Technology Transfer: Overview

- Division of Technology Development and Transfer (DTDT)
- Division of Administrative Management (DAM)
- Division of Policy
- International Activities

## Division of Technology Development and Transfer

- Composed of 5 branches:
  - General Medicine
  - Cancer
  - Infectious Diseases/Medical Engineering
  - Monitoring and Enforcement
  - Technology Transfer Service Center
- Clearinghouse for invention disclosures from all 27 ICs/FDA
- Manages Records

## Role of DTDT

- Assess Inventions
- Manage Patent Prosecution
- Market Technologies
- Conduct Out-Licensing
- Monitor and Enforce Agreements

## Role of DTDT

- Assess Inventions
  - Seek patent protection or license w/out patent
    - NIH Research Tools Policy
      - Any material or method that can be used to further investigation into biological systems or pathways or which can be used to identify potential new pharmaceutical products
    - NIH Patenting Policy
      - Seek if facilitates availability for preventative, diagnostic, therapeutic or other commercial use
      - Seek if further R&D necessary to realize technology's primary use
      - Seek if commercial or public health value warrants expenditure of funds
      - Seek if research has practical utility or reasonable expectation of future practical utility
      - Do not seek if commercialization/transfer can best be accomplished without
  - Waive rights to inventor
  - Dedicate to public domain

## Role of DTDT

- Manage patent prosecution
  - In concert with contract law firms
  - Advise IC's on strategy
  - General patenting model:
    - Invention Disclosure
    - Provisional Patent Application
    - PCT Application
    - National Stage (various countries)

## Role of DTD

- Market Technologies
  - Federal Register
  - OTT list serv
  - Commercial databases
  - Present at various national/international venues in concert with ICs and/or inventors
  - Direct marketing

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## Role of DTD

- Conduct out-licensing
  - Transfer inventions to private sector for further R&D and potential commercialization to benefit public health
  - Aim to commercialize intramural US Federal technologies with the intent of recouping US taxpayers' dollars
  - Negotiate mutually beneficial terms and language with academia, start-ups, multi-national pharma, biotech, med-device, research reagent companies and other Gov Agencies and private foundations
  - Ensure use, commercialization and public availability
  - Gateway to licensing: NIH License Application
  - Typical agreements
  - Non-exclusive vs. exclusive preference

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## Role of DTD

- Monitor and Enforce Agreements
  - Monitor obligations to ensure compliance
  - Coordinate with RAU to enforce payment obligations & intervene if obligations not met
  - Investigate and settle patent infringement cases
  - Initiate and manage 3<sup>rd</sup> party royalty audits
  - Negotiate and settle disputes involving license obligations or royalty audit findings

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## Role of DAM

- Manage royalties
- Conduct operational procurements
- Manage law firm procurements
- Service IT needs of OTT
- Coordinate personnel matters
- Process travel
- Manage facilities

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## Role of DAM

- Notify Licensees of financial obligations
- Collect royalties from Licensees
- Recover patent prosecution costs
- Calculate & authorize IIA payouts
- Reconcile monthly receipts with OFM
- Authorize release of (licensed) material

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## Typical Royalties in NIH Agreements

- Execution fees
- MAR
- Milestone/Benchmark payments
- Sublicensing consideration
- Patent reimbursement costs
- Earned Royalties

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## Royalty Rate Negotiation

- Type of Product
- Stage of Development
- Market Value of Product
- Market Timing
- Scope of Patent Coverage
- Uniqueness of Materials
- NIH "Content"
- Public Health

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## Division of Policy

- Provide policy review & development
- Provide CRADA support
- Provide intramural policy support
- Provide legislative feedback
- Provide input to international technology transfer and intellectual property initiatives
- Handle waivers and FOIA requests

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Thank you!

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