Department of Veterans Affairs Technology Transfer

Bringing Research Advancements for Veterans to Everyone!
Agenda

• Technology Transfer
• Business at the VA
• Scope of VA Portfolio
• Technology Transfer Business Process
  • Invention Disclosure
  • Determination of Rights
  • Assessment of Technology
  • Marketing
  • Licensing
  • Royalty Distribution
• Questions & Answers
• The commercialization of inventions and discoveries made by Government and affiliated researchers
  • Most often the commercialization involves licensing intellectual property to a company which will develop the intellectual property into a product that benefits the public
  • Could involve a collaboration with the inventor(s) through a license or a Cooperative Research And Development Agreement (CRADA)
The mission of the VA Technology Transfer Program (TTP) is to facilitate the commercialization of VA inventions to benefit Veterans and the American Public.

- Review and evaluate VA employee invention disclosures
- Manage collaborations with Universities
- Review CRADAs, Material Transfer Agreements (MTAs) and other Intellectual Property (IP) related agreements
- Provide IP consulting services to VA employees
- Seek development and commercialization partners

- Bringing Research Advancements for Veterans to Everyone (BRAVE)
TTP Organization

• 16 Full Time Employees (FTE) authorized

• Current Staff: 13 FTEs
  • 1 - Director, Dr. John Kaplan PhD, JD, MBA, PE
  • 8 - Technology Transfer Specialists (PhD, JD, MBA)
  • 4 - Program Analysts/Specialists

• Plans for Technology Transfer Specialists at the VAMCs (Atlanta, Ann Arbor)
• Experience - Government, Private Industry, University TTO, Consulting
• Intramural Research Program ($700M)
• 500 new CRADAs/yr.
• Over 100 partnerships with academia
• 497 New Invention Disclosures in FY18
• 255 (65) Patents Filed in FY18
• 72 (20) Patents Issued in FY18
• 18 active license agreements in FY19 (VA only)
  • Est. 100 plus VA & Affiliate license agreements
• $1,100,000 annual license revenue in FY19 (VA only)
  • Est. $2.5MM annual VA & Affiliate license revenue
Representative VA Affiliates

**University of Washington**
- University of Florida
- East Tennessee State University
- University of Tennessee
- Loma Linda University
- Saint Louis University

**Stanford University**
- Arizona State University
- Louisiana State University
- Wright State University

**UCLA**
- Washington University in St Louis
- University of New Mexico
- University of Oklahoma
- University of California Regents
- University of Nevada
- University of Arizona
- University of Utah
- Universidad San Sebastian
- Augusta University
- Rensselaer Polytechnic Institute
- Medical University of South Carolina
- Indiana University
- Wayne State University
- University of Minnesota
- Iowa State University
- University of Southern California
- California Northstate
- Yale University
- Massachusetts Eye and Ear Infirmary (MEEI)
- University of Maryland
- New York University
- NY State University of New York System
- University of Mississippi
- Cleveland Clinic Foundation
- University of South Carolina

**Wisconsin Alumni Research Foundation (WARF)**
- University of Illinois, Chicago
- University of Louisville
- University of Cincinnati

**University of Michigan**
- University of Kansas
- University of Missouri
- University of Nebraska Medical Center
- Vanderbilt University
- Virginia Commonwealth University
- University of Notre Dame

**University of Washington**
- University of Alabama Birmingham
- Georgia State University
- Emory University
- University of Pittsburgh
- University of South Florida
- Texas A&M University System
- Oregon Health & Science University
- The University of Texas Medical System
- Wisconsin Medical College
- Brown University
- Loyola University Chicago
- Boston University
- University of Pennsylvania
- Tulane University

8/15/2019
Our Process

VA Affiliate Inventor Disclosure
Affiliate TTO VA TTP
Determination of Rights
Protection
Assessment
VA or Affiliate Lead
Marketing
Make a Deal
Disclosure

• All VA employees
• Accept the VA or Affiliate Invention Disclosure Form
• VA Certification Form
  • 1 per each VA affiliated inventor
    • Full-Time
    • Part-Time
  • Without Compensation Employee (WOC)
  • Inter-personnel Agreement (IPA)

Source: VHA Directive 1200.18 & 38 CFR 1.656
## Certification Form

PDF, fill in the preamble, answer yes/no, obtain signatures, and email to vattid@va.gov when complete.

In the Determination of Rights process, TTP reviews the VA Certification form and all other available information to determine if the VA has a legal basis to assert rights in the invention.

### Invention Certification Form

Complete one certification for each VA Inventor.

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
</tr>
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<tbody>
<tr>
<td>1. The invention was made during my official VA working hours.</td>
<td></td>
<td></td>
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<tr>
<td>2. At the time of the invention, I had a responsibility to perform research for VA, whether by VA research funding or otherwise.</td>
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<tr>
<td>3. The invention was made with a contribution by VA of:</td>
<td></td>
<td></td>
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<tr>
<td>a) Facilities</td>
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<tr>
<td>b) Equipment</td>
<td></td>
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<td>c) Materials</td>
<td></td>
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<tr>
<td>d) Funds</td>
<td></td>
<td></td>
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<tr>
<td>e) Information</td>
<td></td>
<td></td>
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<tr>
<td>f) Time or services of other VA employees on official duty</td>
<td></td>
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<tr>
<td>4. The invention:</td>
<td></td>
<td></td>
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<tr>
<td>a) Bears a direct relation to my official VA duties</td>
<td></td>
<td></td>
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<tr>
<td>b) Was made in consequences of my official VA duties</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. I am attaching remarks relating to the above.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I hold an academic appointment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please indicate if you have any of the following advanced degrees:

- [ ] MD
- [ ] PhD
- [ ] DO
- [ ] DPM
- [ ] If other, specify: _______

I hereby voluntarily assigns my entire right, title, and interest in and to the above identified invention to the United States Government. I do not desire a Determination of Rights under 37 CFR Part 501.

See 37 CFR Part 501
See 37 CFR 1.600-1.663

If the employee believes that VA is entitled to an ownership interest in the invention, the employee may choose to check “Yes” and waive the DOR process.
Determination of Rights

• **Assessment of Government Rights**
  • Assert Government ownership of the invention
  • Leave ownership of the invention with the inventor
  • Leave ownership of the invention with the inventor subject to the VA retaining a non-exclusive, government use license

• **Employee Has Right to Appeal**

• **VA Asserts Rights**
  • Managed by VA; or
  • Obligations through CTAA/IMA/IIA if jointly owned

Source: 37 CFR 501
Assessment

• Brief Technical Description
• Brief Market Analysis
• Competitive Position
• Barriers to Entry
• Recommendations
Patent Protection

• **Provisional Patent Application**
  - VA contracted patent firm
  - Collaborative process between attorney and inventor(s)
  - Managed by VA Technology Transfer Specialist (TTS)
  - Active marketing during first year informs decision on conversion to a utility patent application

• **U.S. Utility Patent Application**
  - In the absence of a license or strong licensing prospect, only U.S. patent protection is sought
  - Lengthy prosecution process
  - Grant provides 20 year exclusionary right

• **Foreign Patent Rights**
  - Patent Cooperation Treaty Filing
  - Regional/National Filings
Marketing

• Marketing Briefs
• Passive
• Targeted Marketing
• Media Outlets
• Inventor Suggestions
• Inventor’s Publications
Marketing

• Partnership Intermediary
  • Portfolio Management
  • Marketing
  • Licensing Opportunities
  • Industry Contacts
  • Downstream Economic Impacts

https://techlinkcenter.org/labs/department-of-veterans-affairs/

Source: 15 USC 3715
Licensing

• To Commercialize

• Application Process is Codified (37 CFR 404.8)
  • Commercial Development Plan

• Negotiate an exclusive, partially exclusive, or nonexclusive license agreement
  • Fees
  • Royalties
  • Reimbursement of Costs

*No Inventor Involvement During Financial Negotiations*

Source: 37 CFR 404
Royalty Distribution

• First $2,000 to inventor(s), then:
  • 50% to inventor(s)
  • 50% to VAMC where invention was made

Annual cap of $150,000 per inventor

Source: 15 USC 3710 c & VA Policy
VA Affiliated Nonprofits

- Facilitate Research at the VA Medical Centers
- Flexible Funding Mechanism
  - CRADAs
- Office of General Counsel negotiates
- TTP limited interaction

Source: 38 USC 7361, VHA 1200.17
How can VA employees assist?

- Ensure completion of the Invention Disclosure and VA Certification Form concurrent with Academic disclosure (we accept academic disclosures)
- Facilitate the submission of completed forms through your ACOS R&D for review
- Be available for questions from TTP
- Successfully complete the TTP online course via TMS

So what do I do as an AO?

Alexandra Howell
White River Junction VAMC
Path Forward

• Political
  • Updates to the CFR and VA policy
  • New master agreements

• Economic
  • Outreach
  • Staffing

• Technology
  • Modernization
  • IP database in Cloud, intake portal

• Staff: Local Tech Transfer Specialists
• Early stages: initiated effort in October 2018

• Seeking to understand relationships among research funding, invention disclosures, ownership, patents, publications, licenses and revenue to inform decisions across the ecosystem

• Dynamically drive internal/external dashboards to publicize results

• Chief Data Officer: Mr. Phil Gulck (philip.gulck@va.gov; 202.443.5641)
Special Projects

• Million Veteran Program (MVP)
  • Mega bio-bank to study genetic influences on health and disease\(^1\)
  • Combines clinical EHR with patient genetic data to yield new insights in personalized medicine
  • Over 500,000 veterans currently enrolled

• Full leverage of MVP requires partnerships with industry and academia
  • TTP includes one dedicated TTS to focus on technology transfer of MVP inventions and findings

   https://www.jclinepi.com/article/S0895-4356(15)00444-8/pdf
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Technology Transfer Specialists (TTSs)

<table>
<thead>
<tr>
<th>TTS</th>
<th>Contact</th>
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</thead>
<tbody>
<tr>
<td>Northeast:</td>
<td>202.443.5688</td>
</tr>
<tr>
<td>Chris Drabik, JD</td>
<td><a href="mailto:christopher.drabik@va.gov">christopher.drabik@va.gov</a></td>
</tr>
<tr>
<td>West:</td>
<td>813.417.6327</td>
</tr>
<tr>
<td>Lee Sylvers, PhD</td>
<td><a href="mailto:lee.sylvers@va.gov">lee.sylvers@va.gov</a></td>
</tr>
<tr>
<td>Southeast:</td>
<td>202.443.5736</td>
</tr>
<tr>
<td>Benjamin Henry, MBA</td>
<td><a href="mailto:benjamin.henry@va.gov">benjamin.henry@va.gov</a></td>
</tr>
<tr>
<td>Upper Midwest:</td>
<td>202.632.7554</td>
</tr>
<tr>
<td>Ryan Davis, JD</td>
<td><a href="mailto:ryan.davis7@va.gov">ryan.davis7@va.gov</a></td>
</tr>
<tr>
<td>Mid Atlantic:</td>
<td>202.443.5609</td>
</tr>
<tr>
<td>David Marks, JD</td>
<td><a href="mailto:david.marks2@va.gov">david.marks2@va.gov</a></td>
</tr>
<tr>
<td>Million Veteran Program</td>
<td>857.364.4406</td>
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<tr>
<td>Kip Bodi, JD</td>
<td><a href="mailto:kip.bodi@va.gov">kip.bodi@va.gov</a></td>
</tr>
<tr>
<td>Mid Southwest:</td>
<td>202.443.5778</td>
</tr>
<tr>
<td>Kalpana Reddy, JD</td>
<td><a href="mailto:kalpana.reddy3@va.gov">kalpana.reddy3@va.gov</a></td>
</tr>
<tr>
<td>Pattie Cullum, M.Ed.</td>
<td>202.443.5620</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:patricia.cullum@va.gov">patricia.cullum@va.gov</a></td>
</tr>
</tbody>
</table>
Support Staff

• Ms. Cynthia Schwarz
  Invention Disclosure Intake Management
  cynthia.schwarz@va.gov
  202.443.5690

• Ms. Gloria Winford
  Royalty Distribution
  gloria.winford@va.gov
  202.443.5771

• Ms. Alicia Ming
  Patent Administration; CRADA Administration; Administrative Support
  alicia.ming@va.gov
  202.382.2342

• Mr. Phil Gulck
  Data Analytics
  philip.gulck@va.gov
  202.443.5641
Helpful Links

• Intranet:  
  http://vaww.research.va.gov/programs/tech_transfer/

• Internet:  
  http://www.research.va.gov/programs/tech_transfer/

• VA TechLink:  
  https://techlinkcenter.org/labs/department-of-veterans-affairs/

• VHA Directive 1200.18

• TMS learning course “Technology Transfer Program”
• **Email Box:**
  VA Technology Transfer Invention Disclosures
  vattid@va.gov
  202.443.5645

• **POC:**
  John Kaplan, PhD, JD, MBA
  Director, Technology Transfer Program
  john.kaplan@va.gov
  202.632.7271
Questions & Answers

Thank you!