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
Technology Transfer

• 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)
At the VA...

• 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
• 724 New Invention Disclosures in FY19
• 274 Patents Filed in FY19
• 82 Patents Issued in FY19
• 281 active license agreements in FY19
• $1,165,000 annual revenue in FY19
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
- University of Illinois, Chicago
- University of Louisville
- University of Cincinnati
- University of Kansas
- University of Missouri
- University of Nebraska Medical Center
- Vanderbilt University
- Virginia Commonwealth University
- University of Notre Dame
- 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

1/16/2020
Our Process

1. VA Affiliate Inventor Disclosure
2. Affiliate TTO VA TTP
3. Determination of Rights
4. Protection
5. Assessment
6. VA or Affiliate Lead
7. Marketing
8. 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
### Invention Certification Form

Complete one certification for each VA Inventor

| Employee Name, hereby certify that the invention entitled Invention Title, patent application number... |
| Insert Patent Application Number or state "Not Applicable", was made by me or... |
| while I held... | as VA Position Title at VA Facility Name |

#### 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.

#### 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.

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

<table>
<thead>
<tr>
<th>Please answer “Yes” or “No” in the order that the questions appear.</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The invention was made during my official VA working hours.</td>
<td></td>
<td></td>
</tr>
<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>
<td></td>
<td></td>
</tr>
<tr>
<td>3. The invention was made with a contribution by VA of:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Facilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Funds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) Information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) Time or services of other VA employees on official duty</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. The invention:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Bears a direct relation to my official VA duties</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Was made in consequence 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>
</tbody>
</table>

#### Please indicate if you have any of the following advanced degrees.

- [ ] MD
- [ ] PhD
- [ ] DO
- [ ] DPM
- [ ] Other: Specify:

#### I hereby voluntarily assign 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.

- [ ] Yes
- [ ] No

**See 37 CFR Part 501**

**See 38 CFR 1.660-1.663**
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
• Partnership Intermediary
  • Portfolio Management
  • Marketing
  • Licensing Opportunities
  • Industry Contacts
  • Downstream Economic Impacts

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

Source: 15 USC 3715
• 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
• Data analytics used for evidence-based decision-making

• 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
## Technology Transfer Specialists (TTSs)

<table>
<thead>
<tr>
<th>Region</th>
<th>TTS</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northeast</td>
<td>Chris Drabik, JD</td>
<td>202.443.5688 <a href="mailto:christopher.drabik@va.gov">christopher.drabik@va.gov</a></td>
</tr>
<tr>
<td>West</td>
<td>Lee Sylvers, PhD</td>
<td>813.417.6327 <a href="mailto:lee.sylvers@va.gov">lee.sylvers@va.gov</a></td>
</tr>
<tr>
<td>Southeast</td>
<td>Benjamin Henry, MBA</td>
<td>202.443.5736 <a href="mailto:benjamin.henry@va.gov">benjamin.henry@va.gov</a></td>
</tr>
<tr>
<td><del>Atlanta, Birmingham, Augusta:</del></td>
<td>Brandy Wade, PhD</td>
<td>(404) 321-6111 x4827 <a href="mailto:Brandy.Wade@va.gov">Brandy.Wade@va.gov</a></td>
</tr>
<tr>
<td>Upper Midwest</td>
<td>Ryan Davis, JD</td>
<td>202.632.7554 <a href="mailto:ryan.davis7@va.gov">ryan.davis7@va.gov</a></td>
</tr>
<tr>
<td>Mid Atlantic</td>
<td>David Marks, JD</td>
<td>202.443.5609 <a href="mailto:david.marks2@va.gov">david.marks2@va.gov</a></td>
</tr>
<tr>
<td>Million Veteran Program</td>
<td>Kip Bodi, JD</td>
<td>857.364.4406 <a href="mailto:kip.bodi@va.gov">kip.bodi@va.gov</a></td>
</tr>
<tr>
<td>Mid Southwest</td>
<td>Pattie Cullum, M.Ed.</td>
<td>202.443.5620 <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  
  Data Collection; Administrative Support  
  gloria.winford@va.gov  
  202.443.5771

• Ms. Alicia Ming  
  Patent Administration; Royalty Distribution; 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”
Contact

- **Email Box:**
  VA Technology Transfer Invention Disclosures
  [vattid@va.gov](mailto:vattid@va.gov)
  202.443.5645

- **POC:**
  John Kaplan, PhD, JD, MBA
  Director, Technology Transfer Program
  [john.kaplan@va.gov](mailto:john.kaplan@va.gov)
  202.632.7271
Thank you!