

Intellectual Property (IP) Approach

Doing Business With ARPA-H Industry Day
Breakout Session

November 13, 2024



Why You're Here

- Understand Intellectual Property (IP) within the context of the two most likely R&D award instruments proposers may receive from ARPA-H (Other Transactions, or OTs, and Cooperative Agreements, or CAs)
- Ask IP-related questions



Intellectual Property (IP)

- An intangible creation of the human mind, usually expressed or translated into a tangible form, that is assigned certain rights of property
- **Why is it important?**
 - Protection of IP is one of the few specific topics mentioned in the US Constitution (Article I, Section 8, Clause 8) grants Congress the right to create the patent and copyright system
 - The Patent and Trademark Office and the Copyright Office in the Library of Congress are two of the oldest civilian agencies in the Federal Gov't
 - The Founding Fathers wanted authors and inventors to share their creative works with society at-large with the understanding that their rights in those works would be protected for a limited period of time
- **What protects it?**
 - Federal Law
 - Patents, copyrights, trademarks, trade secrets
 - Includes Bayh-Dole, which allows universities, businesses, and non-profit organizations to own and commercialize inventions that are developed through federally funded research programs. *Only* applies to patentable inventions
 - State laws
 - Trade Secrets

IP Protection Methods

Four basic IP protection methods have been created...

Patent	Copyright	Trade Secret	Trademark
• Protects new, unobvious, and useful inventions • Can include utility, design, and plant/animal patents	• Protects original works of authorship embodied in a tangible medium of expression	• Protects secret business information from unauthorized use or disclosure	• Establishes exclusive rights to use marks that distinguish one's goods and services from another

In exchange for making IP public, authors and inventors are granted a limited monopoly to use their IP and prevent others from doing so within their permission.

Once the limited monopoly expires, however, the IP becomes available to society for any one to use within restriction.

IP Terms in ARPA-H Cooperative Agreements

- Comprehensive Cooperative Agreement terms and conditions: <https://arpa-h.gov/engage-and-transition/submission-resources-and-faqs>.
- Terms are prescribed at [2 CFR § 200.315 - Intangible property](#) and [45 CFR § 75.322 - Intangible property and copyrights](#)
- For patents, Government receives a license to practice the invention in accordance with implementation of the Bayh-Dole Act of 1980 (see [37 CFR part 401](#))
- For data, Government may obtain, reproduce, publish, or otherwise use the data produced under a Federal award; and authorize others to do so for a Federal purpose



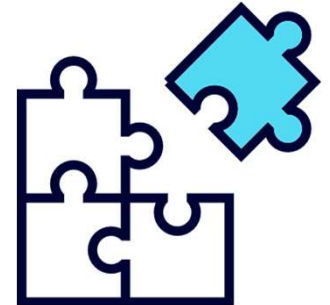
IP Terms in ARPA-H Other Transactions

- Allow terms to be crafted to align with the specific program/project requirements
- As a baseline, ARPA-H seeks a nontransferable nonexclusive license rather than ownership of the subject invention
- Tailored licenses for data
- Process-based tailoring (e.g., disclosure timeframes)
- Sample OT Agreement: <https://arpa-h.gov/engage-and-transition/submission-resources-and-FAQs>



Session Takeaways

- ARPA-H understands and is sensitive to how essential IP is to organizations in the biotech industry. Encouraging investors and creators, while balancing the public's interest, is the goal of the Federal Government.
- ARPA-H isn't looking to own IP created during performance and generally seeks a license in only the IP created during performance.
- ARPA-H's mission is to ensure technologies it invests in are affordable, accessible, and are commercialized.
- Traditional award instruments (i.e., contracts) have strict IP frameworks. ARPA-H intends to use OTs to maximize flexibility in finding IP arrangements that make the most sense for both parties.





Q&A



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