Congressional and Administration Updates

Congressional Update: House Members Introduce Cures 2.0 Legislation

On November 16, Representatives Diana DeGette (D-CO) and Fred Upton (R-MI) introduced the long-awaited bipartisan 21st Century Cures 2.0 Act (Cures 2.0). Reps. DeGette and Upton have been working on Cures 2.0, a follow up to the landmark 2016 21st Century Cures Act, since at least December 2019, and the introduction of this bill follows the June release of a discussion draft and accompanying request for information (RFI). The legislation would authorize the creation of the Advanced Research Projects Agency for Health (ARPA-H), authorize funding for research relief through the Research Investment to Spark the Economy (RISE) Act, and include other provisions related to research, public health, and healthcare delivery. Given that Congress has many competing priorities in the coming months including completing the fiscal year (FY) 2022 appropriations process, it is unlikely that the legislation will become law before the end of the calendar year. Lewis-Burke will
continue to monitor the legislation as it moves through Congress, including as companion legislation is developed in the Senate. More details about Cures 2.0 as introduced can be viewed below.

Research
The legislation would authorize the creation of ARPA-H, a signature Biden Administration initiative designed to drive transformational innovation in health and biomedical research. The bill would task the new agency with accelerating the discovery and application of transformational innovations in health and reducing the human and economic cost of disease. In order to achieve its goals, the bill would direct ARPA-H to:

- Promote high-risk, high-reward innovation;
- Identify and promote revolutionary advances in biomedical and health research that enable new paradigms in health;
- Accelerate transformational health advances in areas that relevant industries by themselves are not likely to undertake because of technical, financial, or other uncertainty;
- Prioritize project investments based on scientific opportunity and uniqueness of fit to ARPA-H strategies and operating practice, together with prospective impact on disease burden, both human and fiscal, including the health care fiscal liability of the federal government; and
- Partner with, and providing funding to, a broad range of institutions, including universities, national laboratories, public sector organization, private companies, nonprofit organizations, and foreign institutions.

The bill would authorize $6.5 billion over three years for ARPA-H, the same amount included in the President’s FY 2022 budget request. This level is higher than what the House and Senate Appropriations Committees, who hold the power to fund the proposed new agency, have recommended for ARPA-H. The Senate would provide $2.4 billion over three years for ARPA-H in its FY 2022 spending bill, while the House would provide $3 billion over three years. Of note, Representative Anna Eshoo (D-CA) has also introduced a bill to create ARPA-H that would authorize $3 billion for ARPA-H. Beyond these differences in topline funding level, a key point of contention across these bills and among members of Congress is whether ARPA-H should be housed within NIH or more broadly within the Department of Health and Human Services (HHS). The Biden Administration’s FY 2022 budget request and Cures 2.0 would place ARPA-H within NIH, while Rep. Eshoo’s legislation would house the agency within HHS and the House and Senate appropriations bills are more ambiguous on its location.

In addition to provisions related to ARPA-H, the research title of the legislation includes the RISE Act, which would authorize $25 billion in funding for research agencies, including $10 billion for the NIH, to provide supplemental funding to universities and independent research institutions to help offset the costs and lost research productivity due to pandemic related closures of laboratories and suspension of research projects.

The legislation also reauthorizes the Research Policy Board until 2026. Created in the 21st Century Cures Act, the Research Policy Board requires the Office of Management and Budget (OMB) to establish an advisory committee, known as the Research Policy Board, that is charged with making recommendations on modifying or harmonizing regulations pertaining to federally funded research in order reduce administrative burden.

Public Health
The legislation would launch several new public health initiatives in preparation for future pandemics, including the development of a National Testing and Response Strategy to assess and develop best practices for testing, vaccine administration, medical supply readiness, domestic drug manufacturing, and data sharing.
infrastructure. Additionally, the legislation would authorize $25 million in funding for the Centers for Disease Control and Prevention (CDC) to carry out a national vaccine awareness campaign and $25 million to strengthen the nation’s immunization information systems across FY 2022 to 2024. Other areas of note include the establishment of a “Learning Collaborative” to further examine implications of “long COVID” symptoms through a series of virtual meetings inclusive of researchers, providers, data scientists, and consumer advocates. Additionally, the legislation would establish NIH grants to research the long-term effects of COVID-19 in children. The legislation also includes the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act, which would invest in programs to address antimicrobial resistance.

Patients and Caregivers
The legislation includes several provisions relevant to improving patient experiences, including authorizing $25 million in funding for FY 2022 through FY 2024 to provide educational programs and training for caregivers. The legislation would also require drug manufacturers to collect and report on patient experiences during clinical trials in a transparent and meaningful way, and require the U.S. Food and Drug Administration (FDA) to take this patient experience information into account when making decisions on drug approvals and authorizations. Cures 2.0 would also seek to improve diversity in clinical trials, by calling on the FDA to provide an updated report on the inclusion of demographic subgroups in trials, commissioning a U.S. Government Accountability Office (GAO) study on barriers to diverse participation in clinical trials, and directing the Secretary of HHS to organize a public awareness campaign to increase understanding of clinical trial participation in minority communities.

Centers for Medicare and Medicaid Services (CMS)
The legislation includes several provisions impacting telehealth policies. Notably, the legislation calls for increased integration of telehealth into state Medicaid programs, and would permanently remove Medicare’s geographic and origination site requirements for providers to be reimbursed for telehealth services. The legislation would also provide the Secretary of HHS with the authority to expand the types of providers that can utilize telehealth in their practices.

The legislation would direct CMS to report to Congress on payment and coverage options for digital therapies that include wearables, digital applications, and platforms. In addition, the legislation seeks to ensure reimbursement for breakthrough devices, defined as devices where no benefit category currently exists.

The legislation proposes an expansion of Medicare coverage for genomic precision medicine consultations. To qualify for reimbursement, the consultation would have to be provided by a licensed clinical pharmacist who has earned a doctoral degree in pharmacy.

The legislation includes the Precision Medicine Answers for Kids Today Act, which aims to increase access to diagnostic testing by establishing a demonstration project and providing federal support for the use of genetic and genomic testing for pediatric patients with rare diseases.

Food and Drug Administration (FDA)
The legislation calls for the FDA to report to Congress on how the agency is fostering greater collaboration and alignment within the agency with respect to the regulation of digital health technologies. The legislation would ask the FDA to discuss how it reviews digital endpoints and digital biomarkers, the acceptance of decentralized trials, the use of digital health technologies in patient-focused development of products, and the use and validation of digital health technology tools.
The legislation calls for the creation of a grant program within FDA for novel designs in the creation of clinical trials for drugs. In awarding funds under the program, the Secretary of HHS should prioritize the incorporation of digital health technologies and real-world evidence in the development of drugs. In addition, the legislation calls on the agency to issue guidance on the use of real-world evidence in evaluating the safety and effectiveness of drugs after they are approved. Additionally, the legislation would direct the Secretary of HHS to create a “Real World Evidence Task Force,” which would be comprised of the Secretary of HHS, the Administrator of CMS, the Commissioner of the FDA, the Director of the NIH, and a private sector designee.

The legislation would direct the FDA to report to Congress on the current state of gene therapy, and the foreseeable challenges the agency expects to face over the next ten years. The legislation also includes a section requiring improved communication between FDA and CMS with regard to breakthrough therapies, fast-tracked products, or products eligible for accelerated approval.

The legislation would create two new institutes at the FDA. One institute would focus on a group of diseases that negatively affects at least one major body system, represents a major disease burden in the U.S., affects at least an estimated 50 million Americans, contributes to increasing health expenditures, for which COVID-19 exacerbates symptoms or causes serious complications, and for which products are approved by the FDA at a lower rate than products for other disease groups including those that have gone through abbreviated pathways. The second institute would focus on diseases that affect fewer than 200,000 Americans individually, affect over 30 million Americans collectively, where over 90 percent of the diseases have no FDA approved therapy, and over 50 percent of the patients are children.

The legislation would direct the FDA to issue revised guidance and provide more clarity regarding the development and submission of chemistry, manufacturing, and control information for breakthrough therapies, fast tracked products, accelerated approvals, and regenerative advanced therapies. Distinct from earlier discussion drafts of Cures 2.0, this legislation would direct the FDA Commissioner to convene a meeting with drug and medical device developers, patients, and other stakeholders to gather recommendations on approaches to encourage the adoption of decentralized clinical trials.

The legislation would amend the Food, Drug, and Cosmetic Act by calling for the inclusion of clinical evidence, patient registries, or other sources of real-world evidence in post-approval studies for accelerated approvals.

Sources and Additional Information:
- Lewis-Burke’s analysis of the June 2021 Cures 2.0 discussion draft is available at https://old.lewis-burke.com/sites/default/files/congressional_update_-_house_members_unveil_cures_2.0_discussion_draft_0.pdf
Policy Update: Decadal Survey on Astronomy and Astrophysics Released

On November 4, the National Academies of Sciences, Engineering, and Medicine (NASEM) released Pathways to Discovery in Astronomy and Astrophysics for the 2020s (Astro2020) decadal survey. Astro2020 represents the consensus recommendation of the astronomy and astrophysics community and will guide significant federal investments by the National Aeronautics and Space Administration (NASA), National Science Foundation (NSF), Department of Energy (DOE), and the U.S. Air Force (USAF). The decadal priorities are couched within themes intended to drive forefront scientific discovery and requisite research infrastructure (e.g., multi-billion dollar space- and ground-based telescopes) and policies (e.g., promotion of diversity, equity, and inclusion) to achieve them. While recommendations are non-binding, federal agencies rarely deviate from executing them assuming budget availability. Congress also uses decadal survey priorities to guide annual appropriations spending and in exercising its oversight role over agency spending.

COVID-19 significantly disrupted the Astro2020 steering committee’s ability to develop and draft the report. As a result, funding for decadal priorities is reflected in pending Fiscal Year (FY) 2022 appropriations legislation or as part of the Build Back Better reconciliation bill. The status of agencies’ FY 2023 budget planning will similarly impede many of Astro2020s recommendations from inclusion in the next President’s budget request. Regardless, it is expected that stakeholders (including universities, facility management organizations, scientific societies and advocates, etc.) will attempt to exert pressure on Congress and federal agencies to begin planning and implementing decadal priorities as soon as possible.

An analysis of Astro2020’s recommendations, including key areas that will drive future opportunities, is included below.

Major Missions and Competitive Opportunities

The top recommended “Great Observatories” (GO) flagship space mission is a six-meter Large Ultraviolet/Optical/Infrared (LUVOIR-B) telescope. This is a compromise between two mission concepts; a larger LUVOIR concept (LUVOIR-A) and the Habitable Exoplanet Observatory (HabEx), the latter of which would focus more on exoplanet imagery. The Committee members deemed LUVOIR-A to be too costly and technically difficult while HabEx “may fall short of providing a robust exoplanet survey.”

In order to stay on schedule and cost during development of LUVOIR-B, the Committee recommended that NASA’s Astrophysics Division (APD) should establish an $800 million “Great Observatories Mission and Technology Maturation” program. The purpose of this program, learning from the technically challenging development of the James Webb Space Telescope, would be to conduct LUVOIR-B’s technology maturation during much of the current decade to ensure readiness before mission development in the 2030s and launch in the early 2040s. After the first six years the missions funding would be transferred out of the technology maturation programs and into the specific mission development line. Flagship Far-Infrared (Far-IR) and X-ray “Great Observatories” are also 2 recommended, although technology maturation efforts would not commence until the latter half of the decade. While flagship missions are managed and developed by NASA Centers, scientific instruments are frequently competitively solicited and awarded to universities and their industry partners.

The Committee acknowledged the gap between the cost and capability of APD’s competitive class of “Explorer” missions and the multibillion-dollar flagship missions. To bridge this divide, Astro2020 recommended a new “Probe” class of competed missions cost-capped at $1.5 billion. Rather than endorse specific Probe mission concepts, the decadal recommended general “priority areas” that future mission proposals would address; a Far-IR imaging or spectroscopy mission and an X-ray mission. Both priority areas
dovetail with the future GOs, and will inform their scientific priorities. NASA anticipated that a Probes mission line would be a top Astro2020 recommendation and included an unspecified amount of funding in its FY 2022 budget request to begin implementation.

For ground observatories, the survey recommended NSF pursue a two-telescope U.S. Extremely Large Telescope (US ELT) program. Complimentary capabilities of both the Giant Magellan Telescope (GMT) and the Thirty Meter Telescope (TMT) would provide full-sky coverage and assure observations of rare objects regardless of time or location of occurrence. Both telescopes emerged from recommendations in the prior decadal (Astro2010), are at varying stages of development, and have received funding from non-NSF partners. The decadal recommended NSF invest in the US ELTs to acquire 25 percent of observing time on each telescope, or if only one of the telescopes is deemed viable, NSF should invest up to 50 percent. The other two ground-based projects – the Cosmic Microwave Background-Stage 4 (CMB-S4) and Next Generation Very Large Array (ngVLA) – were also recommended for NSF funding. The former could begin construction in the first half of the decade and through a partnership with the Department of Energy, and the latter would notionally begin formal development in the second half.

The Committee’s highest priority for sustaining activity for ground-based observations is to augment and expand NSF’s Astronomy Mid-scale program. Encompassing missions from $4 million to $120 million, including the Mid-Scale Innovations Program (MSIP), and Mid-scale Research Infrastructure (MSRI), the survey highlights how these programs ensure robust capabilities for basic research. The Committee recommends expanding the astronomy funding levels of these programs, including dedicated calls to upgrade instrumentation at existing facilities, with a focus on 4-10 meter telescopes, and for specific priority areas including, time-domain astrophysics, highly multiplexed spectroscopy, and radio instrumentation.

**Balanced Agency Portfolios**

The survey continues a trend of past decadals in highlighting the importance of a balanced and broad portfolio that includes small, medium, and large missions and growth in individual investigator grant programs. The Committee also recommends several smaller missions and projects that make up both sustaining and foundational science activities. Within the sustaining activities, the Committee recommends NASA establish a space-based multi-messenger and time-domain astronomy suite accommodated by future Explorer missions. Much of this work builds on the recommendations made in the Astro2010 including anticipated science outcomes of the Vera Rubin Observatory, the Nancy Grace Roman Space Telescope, and the Laser Interferometer Gravitational-wave Observatory (LIGO).

NASA primarily funds space-based astrophysics research through the through the Astrophysics Research and Analysis Program (APRA), Astrophysics Theory Program (ATP), Astrophysics Data Analysis Program (ADAP), and the Exoplanet Research Program (XRP). These programs are oversubscribed due to high 3 proposal pressure and underfunding; therefore, the Committee recommends increasing all the individual investigator astrophysics grants programs at NASA by 20 percent to restore healthy, competitive, success rates. The Committee also notes that APD investment in basic technology grants is too small to fuel the innovative projects needed to enable future missions and recommends funding for the basic technology development portion of APRA be significantly increased.

For ground-based astronomy, the survey highlighted growing concerns that increased large facilities’ operations and maintenance (O&M) costs will significantly impact grants budgets. This is a historical challenge that has placed downward pressure on astronomy grant funding and which both NSF and the National Science Board have sought to address. O&M costs are expected to increase when new telescopes begin operations in
the next several years and absent large and sustained increases to the NSF Astronomy Division’s (AST) overall budget impacts to grants funding will only increase. The problem is severe enough that the decadal recommended funding for any new observatory (i.e., US-ELTs, CMB-S4, ngVLA) be incumbent on NSF working to find a resolution. Further, the survey recommends AST establish a review of its facilities portfolio every five years similar to NASA’s Senior Review process. This process would ensure NSF sponsorship of current and future facilities is aligned to overall scientific and strategic priorities.

The Committee acknowledges the competing priorities at NSF between funding facilities’ operation and maintenance and competitive research, but notes that due to declining funding rates the success rate at NSF has fallen to below 20 percent. The Survey recommends NSF increase funding for individual investigator Astronomy and Astrophysics Research Grants by 30 percent by 2028, in order to restore success rates to a healthy competitive level.

**Changes to Funding Policies**
The Astro2020 decadal survey places an increased importance and attention on human investments and public impacts in multiple ways. First, the Committee concluded that there is a lack of diversity among astronomy faculty and recommends funding agencies should increase funding incentives for improving diversity among astronomy and astrophysics faculty. This could be done by leveraging current early-career faculty programs, such as the NSF Faculty Early Career Development Program (CAREER) and the NSF Alliances for Graduate Education and Professoriate (AGEP), to incentive faculty diversity. Further, the Committee found that previous NASA, NSF, and DOE funding programs focused on training and partnerships with minority-serving institutions (NSF PAARE, NASA MUCERPI, DOE FaST) have been defunded and the Committee recommends reinvesting in such professional workforce development diversity programs. In order to better understand the impacts of such diversity programs in funding opportunities, or lack thereof, the survey also recommends NASA, NSF, and DOE implement a cross-agency working group to establish a consistent format and policy for collecting, evaluating, and publicly reporting demographic data and indicators pertaining to outcomes of proposal competitions.

**CMMC 2.0 Overview**
The Department of Defense Office of Acquisition and Sustainment (DOD A&S) has provided updated guidance on the Cybersecurity Maturity Model Certification (CMMC) resulting in the creation of CMMC 2.0. The CMMC is a framework of standards for cybersecurity practices across academic, industry, and other Defense Industrial Base (DIB) organizations that contract with and support DOD. The framework was created to enhance the protection of Controlled Unclassified Information (CUI) due to concerns of an increase of cybersecurity attacks against contractors and organizations that support the DOD.

The DOD conducted an internal assessment and reviewed hundreds of public comments to create CMMC 2.0 with the goal of making the process of obtaining CMMC accreditation more streamlined and flexible, especially for small and medium sized businesses. Lewis-Burke recommends that staff who handle cyber or information security, as well as contracting officers, are aware of and understand these new requirements.

**What is CMMC?**
The Cybersecurity Maturity Model Certification (CMMC) is a new framework of standards for cybersecurity practices across academic, industry, and other Defense Industrial Base (DIB) organizations that contract with and support the Department of Defense (DOD). The goal of CMMC is to enhance the protection of Controlled Unclassified Information (CUI) across the supply chain through a standard
assessment model and framework for compliance, including a hierarchy of cybersecurity regulations and practices. DOD published an interim rule on September 29 in the federal register for how this framework would be implemented. In March 2021, the DOD conducted an internal assessment of the CMMC program based on the hundreds of public comments they received. That resulted in the update of the program structure in November 2021, creating CMMC 2.0.

**Why did DOD establish CMMC?**
The CMMC program was developed in response to concerns about cyberattacks against the contractors and organizations that support the DOD. DOD officials have discussed the potential for adversaries to hack contractors for a variety of purposes. This could include espionage or could also include other goals such as driving small defense contractors out of business or modifying requirements on a system to cause critical failures down the road. Due to previous findings that a significant number of contractors and subcontractors have not sufficiently complied with current cybersecurity standards requirements, the Department is establishing and implementing the CMMC framework to better protect the DIB.

**How does CMMC work?**
The CMMC 2.0 framework has three levels of requirements and processes that organizations must implement to ensure the security and protection of CUI related to a DOD-funded project. The CMMC Accreditation Body (CMMC-AB), working alongside DOD, has created the requirements for organizations to be CMMC certified and is currently commissioning Third Party Assessment Organizations (C3PAOs) C3PAOs to conduct CMMC assessments and certify CMMC certifications. The C3PAOs will be tasked with conducting assessments on Level 2 and 3 contractors. As of November 2021, the three levels are as follows:

- Level 1: Foundational
- Level 2: Advanced
- Level 3: Expert

Organizations applying for grants or contracts from the Department will have to have the appropriate CMMC level specified in that grant or solicitation at the time of award. In most cases, fundamental research would require CMMC level 1, which would ensure basic cyber hygiene practices such as monitoring and limiting access to operating environments (laboratories) and information systems; scanning systems for and maintaining updated systems to protect against malicious code; and limiting data access from DOD-sponsored projects to authorized users.

CMMC Level 2 requires adoption of the National Institutes of Standards and Technology’s (NIST) standards for protecting CUI, known as Special Publication (SP) 800-171 Rev. 1. Level 2 includes a subset that involves information critical to national security which will require an assessment by a C3PAO. The other subset of level 2 would not involve information critical to national security, and associated contractors will only be required to conduct self-assessments.

It is expected that only a small number of contracts involving the most sensitive or classified information will require CMMC level 3 certification.

**What are the differences between CMMC 1.0 and CMMC 2.0?**
The CMMC 1.0 framework had five levels of requirements and processes that organizations were
required implement to ensure the security and protection of CUI related to a DOD-funded project. As stated above, CMMC 2.0 framework now only has three levels of requirements. This change was created by eliminating levels 2 and 4 of the 1.0 framework and removing CMMC-unique practices and all maturity processes from the CMMC model:

**CMMC 1.0**
- Level 1: Basic Cyber Hygiene
- Level 2: Intermediate Cyber Hygiene
- Level 3: Good Cyber Hygiene
- Level 4: Proactive
- Level 5: Advanced/Progressive

**CMMC 2.0**
- Level 1: Foundational
- Level 2: Advanced
- Level 3: Expert

The DOD Office of Acquisition and Sustainment (A&S), which is more heavily involved in the CMMC 2.0 implementation compared to 1.0 (that was mostly controlled by CMMC-AB), states that this change creates a more streamlined process; reduces assessment costs by allowing companies at levels 1 and 2 to conduct annual self-assessments to demonstrate compliance ultimately helping more small and medium sized businesses; and allowing more flexibility through the implementation of waivers for CMMC requirements under certain limited circumstances. Further, the CMMC 1.0 model also required that all DOD contractors undergo C3PAO assessments for CMMC compliance, but CMMC 2.0 only requires levels 2 and 3 to undergo a C3PAO assessment.

**Will this affect my organization?**
Yes. Eventually, CMMC requirements of varying levels will appear on all DOD solicitations for contracts and grants that exceed the micro-purchase threshold of $10,000. Although a number of higher education and research associations have argued that DOD should exempt fundamental research from CMMC requirements, it is unlikely that DOD will exempt certain categories.

DOD’s analysis found that the department awards on average 485,859 contracts and orders that would be affected to 39,204 unique awardees, of which 262,509 awards are made to 26,468 small entities. DOD also acknowledges that R&D in the physical, engineering, and life sciences fields would be among the top five industries impacted by the rule.

**When will CMMC be implemented?**
The changes in CMMC 2.0 will be made through the rulemaking process in 1) title 32 of the Code of Federal Regulations (CFR), to establish the CMMC 2.0 program; and, 2) title 48 CFR, to implement any needed changes to the CMMC program content in 48 CFR. Both rules are currently open for public comment and program requirements will not be mandatory until the title 32 CFR and title 48 CFR rulemaking processes are complete.

Previously the DOD announced that they would gradually integrate the requirements by distributing pilot programs starting with 15-20 in year one. Those CMMC piloting efforts have been suspended until CMMC 2.0
changes become effective. The timeline of implementation remains the same, with the DOD broadly adopting CMMC requirements across all contracts, solicitations, and grants on October 1, 2025.

**What do I need to do?**
Lewis-Burke recommends that staff who handle cyber or information security, as well as contracting officers, are aware of and understand these new requirements. Lewis-Burke will continue to report on new developments and updates on the CMMC.

**Additional Information:**
- Information on the CMMC framework can be found [here](#).
- DOD’s September 29 interim rule implementing the CMMC, “Assessing Contractor Implementation of Cybersecurity Requirements,” can be found [here](#).
- November 2021 CMMC 2.0 Updates and Way Forward Interim Rule can be found [here](#).
- DOD launched a website to help explain CUI policy and training, and to provide a registration of CUI categories [here](#).

[Funding Opportunity: DARPA Releases Automating Scientific Knowledge Extraction and Modeling BAA](#)

The Information Innovation Office (I2O) of the Defense Advanced Research Projects Agency (DARPA) released a broad agency announcement (BAA) for the Automating Scientific Knowledge Extraction and Modeling (ASKEM) program. ASKEM develops a knowledge-modeling-simulation ecosystem using artificial intelligence (AI) to help experts manage heterogeneous data. Solutions will be demonstrated in exercises involving epidemics (i.e. COVID-19) and space weather impacts. ASKEM’s goal is to enable future leaders to prevent damages by adversaries, disasters, and global changes. Modeling automation tools sought must:

1. “extract model components from documents and code while abstracting away from implementation details like math framework, language, and platform;
2. decompose and compose distinct model and simulator components;
3. integrate all elements and processes in the modeling pipeline to enable full traceability and reach back to knowledge during modeling and simulator design.”

ASKEM will be develop and demonstrate technologies in the following four technical areas (TAs):

- TA1: Machine-assisted knowledge discovery and curation
- TA2: Machine-assisted modeling
- TA3: Machine-assisted simulators
- TA4: Workbench for HMI and Integration

DARPA anticipates funding multiple awards for TAs 1-3 and a single TA4 award. Each proposal may address any single TA, a combination of TA1 and TA2, or a combination of TA2 and TA3. No other TA combinations will be accepted. Further details can be found in the full BAA. All responsible sources are eligible to apply. Cost sharing is not required. A Proposers Day will be held on **December 8, 2021**. Abstracts are due on **December 13, 2021, at 12:00 PM ET**. Full proposals must be submitted no later than **February 7, 2022, at 12:00 PM ET**. The full BAA can be found on [www.grants.gov](http://www.grants.gov) under funding opportunity number “HR001122S0005” or [here](#).