

Research News Quarterly

FEBRUARY 2019

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Letter from the Editor

Our feature article this month is an interview with the director of the Veteran Health Administration’s Million Veteran Program (MVP), Sumitra Muralidhar, PhD. In the interview, Dr. Muralidhar reports on the progress of MVP, survey questions dealing with respiratory and sleep-related issues, and opportunities for pulmonary investigators in the VA system to access MVP data to study respiratory disorders. She also discusses similarities between MVP and the All of Us Research Program, part of the federal Precision Medicine Initiative, and how the programs complement each other.

We have included a section outlining new activities, workgroups, and sessions at ATS 2019 in Dallas, including an update on the BEAR Cage competition, now in its fifth year; creation of the new PhD, Basic and Translational Scientist Working Group; and advocacy-related sessions.

Next, we move to NIH for our series on institute intramural programs, which this month focuses on the NHLBI’s expansive Division of Intramural Research, followed by an announcement of NIH’s Rare Disease Day on Feb. 28, 2019. Shifting to funding opportunities, we outline those available through the Department of Defense’s Congressionally Directed Medical Research Programs. Recently, there have been moves at the federal level that have significantly affected NIH’s fetal tissue research, and the Quarterly reports how the ATS is working to support this research.

We close out the Quarterly with two advocacy-related pieces: the first on asthma advocacy by ATS Public Advisory Roundtable and Research Advocacy Committee member Tonya Winders and the second on our Washington Office’s outlook on health research funding in 2019.

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INTERVIEW WITH Sumitra Muralidhar, PhD, Program Director, Million Veteran Program, Veterans Health Administration Research and Development Program

Q: Dr. Muralidhar, you have a prominent position in the VHA Research and Development Program as Program Director for the Million Veteran Program (MVP). Your responsibilities include overseeing collection and use of clinical and genomic data from over 600,000 veterans. Can you summarize the types and state of the data collection and how the data are being used? What are some of the timelines and milestones are for the program?

A: I'm happy to report that as of Jan. 30, 2019, we have enrolled 730,748 veterans in MVP and are getting closer to reaching our goal of at least one million. Active data collection from our participants include self-reported data on demographics, health and health history, family health history, lifestyle, deployment, and military exposure through the Baseline and Lifestyle Questionnaires.

Much of these data such as lifestyle, behavioral, nutritional intake, and exposure data are not very well documented in their electronic health records, and therefore the questionnaires provide valuable data points. We collect blood samples from every participant from which molecular data are obtained.

Currently, every sample we obtain gets genotyped on a customized Affymetrix Axiom Array. Genotype data from approximately 460,000 participants have completed quality control checks and have been imputed. Passive data collection includes extraction, cleaning, and curation of the rich clinical data from the electronic health records of the enrollees.

Currently, clinical data, questionnaire data, and imputed genotype data are available to approved researchers who are participating in the alpha, beta, and gamma testing of the access process. Thirty-one research projects have been approved for funding and are in various stages from start-up to completion.

These projects were funded through existing peer-review mechanisms through the Office of Research and Development. The projects are largely in the areas of mental health (PTSD, schizophrenia, bipolar disorder, multi-substance abuse), cancer, cardiovascular and cardiometabolic diseases, diabetes, chronic kidney disease, age-related macular degeneration, tinnitus, and Gulf War Illness. Over 70 abstracts have been presented at national and international scientific

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Dr. Muralidhar Interview *(Continued from page 2)*

meetings, and 12 papers have been published, including two recently in *Nature Genetics*.

Additionally, in FY18 we initiated a new pilot program to provide MVP access to Career Development Award applicants in Biomedical and Clinical Science Research Services to train early research scientists in data science and big data analytics in the VA.

We have committed funding for sequencing 100,000 whole genomes, and these data are being generated. In FY18 we conducted a metabolomics pilot on 2,000 plasma samples and are in the process of analyzing the data. The goal is to generate deeper and multi-layered data on our participants over time, so that we can better understand the molecular and biochemical basis of disease. Our ultimate goal is to translate research discoveries from MVP into better treatments and diagnostics for our veterans and the population at large. Over the next two to three years, we expect to make the data more broadly available to the larger scientific community within and outside the VA.

Q: Have there been challenges in the implementation and management of MVP that were not foreseen?

A: Implementing a large and complex program such as the MVP certainly has its challenges, some expected and some unforeseen. One thing that we did differently when compared to other similar cohorts such as the UK Biobank is that we did not wait to complete enrollment of our one million cohort before opening up the data for research. An analogy we often use is that we are building the plane as we're flying it.

Continuing to maintain recruitment and enrollment and maintaining our cohort, while also establishing governance for data use and implementing the alpha-beta-gamma testing of data access have proven to be quite challenging. Furthermore, our limited funding has restricted how rapidly we can accomplish certain tasks, but despite that, we have been able to keep the program on course and moving in the right direction. I'm very proud of what our national MVP team has accomplished.

One of our biggest challenges has been the lack of IT resources to host a central, secure, and agile computational

environment within the VA that would allow thousands of researchers access to the data simultaneously. To advance and to translate scientific discoveries that have the potential to transform towards that end, we are working on establishing an external VA Data Commons, where research-ready MVP data can be made accessible to the broader research community. Making VA data a national resource is one of Dr. Rachel Ramoni's (VHA's chief research and development officer) strategic goals.

Big data brings with it the challenge of computational resources needed for processing large numbers of whole genomes, for example, or mining the rich electronic health record data. Towards that end, we have established a partnership with the Department of Energy (DOE) to leverage the VA's and MVP's big data and DOE's high-performance computing infrastructure and expertise to enable scientific discovery and advancement of precision care in the VA.

Q: You have served as a liaison between the VA and the White House during the planning for and implementation of President Obama's Precision Medicine Initiative. How would you compare MVP to the Precision Medicine Initiative in terms of goals, implementation, and accomplishments to date?

A: MVP was officially launched in 2011, with the ground work starting a couple of years before that, and so it was in existence well before President Obama announced the national Precision Medicine Initiative (PMI). Roughly 400,000 veterans had already enrolled in MVP by the time PMI was announced. It was my great privilege to represent the VA and be a part of the planning and implementation of President Obama's Precision Medicine Initiative, along with several other federal agencies. There were a number of new programs launched as part of PMI, including the All of Us (AoU) Research Program and the Cancer Moonshot. MVP is also considered a part of the overall initiative and in fact, we enrolled our 500,000th enrollee in 2015 at the Disabled Veterans of America (DAV) national convention in Atlanta, which President Obama attended and announced the milestone.

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Dr. Muralidhar Interview *(Continued from page 3)*

Both MVP and AoU share the larger goal of enabling precision medicine. Both programs aim to enroll ethnically and racially diverse participants. There are some differences in the demographics of the participant pool (90 percent males in MVP, for example), design and implementation of the two programs. However, I believe that they complement each other and there are opportunities for future collaboration between the programs in ways that can accelerate and amplify scientific discovery. Imagine two cohorts in the U.S., each a million strong!

Also of note, the VA is participating as a health care provider organization in AoU and enrolling veterans. We will have a subset of veterans in both MVP and AoU, and that can provide unique opportunities for collaborative research.

Q: Many of the early projects that have been undertaken in MVP have dealt with problems that are particularly common among veterans, including suicide, PTSD, tinnitus, and cardiovascular disease. As you know, respiratory disorders, such as COPD, asthma, lung cancer, idiopathic pulmonary fibrosis, and sleep-disordered breathing, also are very common among veterans and likely have genetic contributions to their pathogenesis. What opportunities are available for pulmonary investigators in the VA to access data in MVP to study these disorders?

A: I agree that these areas—COPD, asthma, lung cancer and sleep-disordered breathing, etc.— are extremely relevant and important for our veterans. The beta and gamma MVP projects were selected for funding through the existing Merit Review funding mechanism in the Office of Research and Development (ORD), the betas through the Biomedical Laboratory Research and Development (BLR&D) Service and the Gammas through all four research services within ORD. There were no topical areas preferentially announced in the Request for Applications, and all VA researchers, including pulmonary investigators, were allowed to submit proposals. The proposals selected for funding through the peer-review process reflect the most meritorious applications that emerged from this

process and are in the areas currently represented in the beta and gamma projects.

As we expand MVP data access more broadly and routinely through the Merit Review and Career Development Award mechanisms within the VA, and also open it up to other non-VA funding mechanisms in the future, I expect that we will cover all disease areas represented in MVP and among veterans. One of our major limitations has been a computational environment that can handle large number of investigators. We are earnestly working on a potential solution for that.

Q: In her interview for the American Thoracic Society's Research News Quarterly in 2017, Dr. Ramoni stated that "MVP will be the basis of Merit and Career Development Awards and will elevate them with the breadth and quality of its data." Are there now opportunities for pulmonary investigators to apply for VA Merit Review and Research Career Development Awards that would be based on use of MVP? Are there other funding mechanisms within the VA to support this type of investigation using MVP?

A: In FY 2019 the only mechanism open to all investigators for accessing MVP data is the Career Development Award (CDA) mechanism that we are piloting through BLR&D and Clinical Science Research & Development (CSR&D) Services. There are several early investigators who have taken advantage of this opportunity, and we are delighted to see that happen. We expect to open both Merit Review and CDA mechanisms in FY2020.

Q: Veterans who are participating in MVP fill out surveys related to their military-related exposures, lifestyle, and health. Do these surveys contain questions relevant to veterans with respiratory or sleep-related disorders or their susceptibility to such illnesses?

A: The MVP questionnaires contain questions about smoking habits, health, and family history of chronic lung disease (COPD, emphysema and bronchitis), asthma, lung cancer, sleep apnea, and sleep quality, as well as exposures to burn pits, solvents and fuels, petroleum combustion products, and other materials.

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Dr. Muralidhar Interview *(Continued from page 4)*

Q: Part of the stated goals of MVP is to improve health and treatment not only of veterans but also of the broader U.S. population. Will pulmonary investigators outside of the VA have access to the data in MVP and to associated VA funding opportunities?

A: Currently, as was the case with the alpha, beta, and gamma test projects, several investigators from our academic affiliates have collaborated with VA researchers through Work Without Compensation appointments at the VA and are accessing MVP data within the VA computing environment. In the future, when we have established the external VA Data Commons, investigators outside the VA will be able to access the data with appropriate training and approvals.

Q: How is the VA supporting educational opportunities for investigators interested in participating in MVP? We're aware of a few programs for training within the VA in data science, including the Big Data Scientist Training Enhancement Program. Are there similar programs for VA investigators to learn more about genomic medicine?

A: That is a great question. The VA is participating in the Big Data Scientist Training Enhancement Program (BD-

STEP), with 10-12 candidates being accepted annually. Currently, MVP is accepting some of those candidates annually. One of the currently approved MVP projects for a One VA BD-STEP fellow is studying lung cancer. Adding big data analysis, including MVP to the Career Development Program, as a pilot which began in FY18 is another attempt on our part to assess interest, training needs, and foster the next generation of researchers in big data science within the VA.

Q: The ATS represents more than 16,000 scientists and clinicians in the U.S. and internationally interested in pulmonary, critical care, and sleep disorders. What aspects of MVP would be most important for our membership to be familiar with?

A: I think being familiar with the types of data that are currently collected, particularly as they relate to pulmonary diseases, and being aware of timelines for new Requests for Applications through ORD, and other funding opportunities as they become available, will be helpful to your membership.

Thank you, Dr. Muralidhar. We look forward to your presentation at the VA Outside Organizational Session on Monday, May 20 at 12:15p.m. in Dallas. ■

ATS CONFERENCE

ATS BEAR Cage Competition Enters 5th Year at ATS 2019

The BEAR (Building Education to Advance Research) Cage is a competition held annually at the ATS International Conference. Young career professionals apply to pitch their innovative research proposals to a panel of translational science experts working in academia, government, or industry. The three finalists receive complimentary conference registration to present their findings. The winner of the competition receives a \$10,000 prize to help fund their research; the runners-up both receive \$2,500; and all three get assigned a distance mentor from the Drug Device Discovery and Development Committee for one year.

In 2014, the DDDD Committee saw an opportunity to fill a gap between research and science with the BEAR Cage competition. One of the committee's benchmarks for the year was to recommend strategies to enhance interactions between industry, university, and government scientists to further enhance translational research and innovation.



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ATS Conference: Bear Cage Competition *(Continued from page 5)*

Using the popular television series “Shark Tank” as a model, the DDDD Committee opens the application window every winter, and after a thorough review selects three finalists to present their findings on stage at the International Conference. Each finalist has 10 minutes to pitch his or her findings, 10 minutes to answer questions from the panel, and 10 minutes to take questions from the audience.

Winner of the 2016 BEAR Cage Jake Brenner, MD, PhD, from the University of Pennsylvania, said, “The BEAR Cage award was truly pivotal for me getting a K08 grant, a tenure-track faculty position, and a collaboration with a pharmaceutical company to continue developing our therapeutic devices.”

The BEAR Cage may have started as a way to bring innovation and science closer together at the ATS, but it’s become a launching pad for entrepreneurial researchers looking to work with academia, industry, or technology and has brought recognition and opportunities to the finalists. For more information, please see the FAQ page on our website.

The first Bear Cage winner Josh Fessel, MD, now a program officer at the NHLBI in the Division of Lung Diseases, credits part of his professional success to the competition, “The decision to climb into the BEAR Cage has proven to be one of the best professional decisions I’ve ever made! I’ve gained invaluable knowledge and experience that I simply couldn’t have gotten any other way. That knowledge and experience has direct relevance to what I do on a day-to-day basis. The perspective, the mentoring, and the professional interactions that I’ve been lucky enough to have thanks to the BEAR Cage make me better at my job, no question.”

At ATS 2019, we’re looking forward to collaborating with the Science & Innovation Center, where the event will take place. Anyone interested in networking or learning more about the next generation of young researchers should seek out the BEAR Cage competition Monday afternoon, May 20, where you’ll have a chance to ask questions of the finalists, mingle with the judges, and meet up-and-coming innovation “rock stars.” ■

NEW ATS PhD WORKGROUP

The PhD and Basic and Translational Scientists Working Group: Focusing on a Key Constituency of the ATS Membership

By Blanca Camoretti-Mercado, PhD, Chair, PhD & Basic & Translational Scientists Working Group

At the May 2016 ATS Board of Directors meeting, then President Dr. Atul Malhotra appointed a group of assembly chairs—Blanca Camoretti-Mercado of Respiratory Structure & Function, Naftali Kaminski of Respiratory Cell & Molecular Biology, and Mitch Olman of Allergy, Immunology, & Inflammation—to identify concerns of PhD members, recommend ways of increasing the ATS’s value to these members, and improve their experience within the ATS.

About 30 ATS members, representing 12 different assemblies, exchanged ideas and deliberated during the following year, and reviewed some statistics in order to understand the state of PhD members of the Society. A follow-up meeting was organized during ATS 2017 to review the findings, discuss issues, set a plan to address them, and define goals and strategies. According to discussions, PhD members most valued the opportunities that the International Conference and the Society offered for professional advancement and resume building. Dissatisfactions included the cost of attending the conference and the limited programming for basic scientists, including limited activities for non-clinician scientists outside the conference program.

To improve the PhD experience, partnerships were recommended with other Society groups, including the Members in Transition and Training and Education committees, the Planning and Evaluation committee, the Science and Innovation Center, the assembly program committees, the Basic Science Core Working Group, and the ATS journals. A survey to assess the needs of the membership at large was also recommended. Finally, making the PhD group an official entity within the ATS was considered a valuable means to ensure the resources and time necessary to accomplish the

ATS Conference *(Continued from page 6)*

goals, guarantee continuity, and facilitate achievement. These conclusions were presented to the BOD, which expressed its support for the work of the group.

In collaboration with the Science and Innovation Center, the first reception for PhDs and other basic science researchers” was held during ATS 2018. Over 100 individuals attended to learn about the group and to network, and a survey to assess needs was completed by over 50 attendees.

The PhD and Basic and Translational Scientists Working Group started officially on Jan. 1, 2019, chaired by Dr. Blanca Camoretti-Mercado and co-chaired by Drs. Tom Mariani and Beth Moore. The working group includes members of most ATS assemblies. The long-term goal is “to improve the value and the experience of ATS members with professional efforts that are either predominantly or specifically basic or translational oriented research.” In addition, the working group will promote diversity, including the training background, of participants on various ATS committees. Planning for the second reception at ATS 2019 is underway. We invite all Society members to attend! ■

ADVOCACY SESSIONS AT THE ATS CONFERENCE

Register for the 2019 ATS Conference Advocacy Workshop!

609 (WS6) HEALTH POLICY ADVOCACY 101: EFFECTIVELY INFORM YOUR ELECTED OFFICIALS

Tuesday, May 21, 11:45 AM-1:15 PM

This session is intended to provide an introduction to federal and state advocacy. Using a mix of didactic lectures and small-group role playing, attendees will learn how to prepare for and participate in legislative meetings, write letters to the editor, and deliver media messages using social media.

Advocacy Mini-Symposium

B91, HAVE A BIGGER IMPACT! EFFECTIVE STRATEGIES TO UTILIZE YOUR PROFESSIONAL EXPERTISE TO ADVOCATE FOR YOUR PATIENTS AND YOUR COMMUNITIES

Monday May 20, 2:15 PM - 4:15 PM

This session will describe effective strategies to advance the respiratory health of patients, communities, and populations.

Breathing Better Alliance Advocacy Meeting

Monday, May 21, 11:45 AM. – 1:15 PM

Open meeting featuring federal legislative updates on NIH and CDC funding, tobacco, clean air and other issues.

Lunch will be served

RSVP to Nmoore@thoracic.org

OTHER CONFERENCE SESSIONS & ACTIVITIES

Visit the ATS Science and Innovation Center!

Open Sunday, May 19, 7:15 AM – 5:00 PM through Tuesday, May 21, 4:30 PM

The Science & Innovation Center is a forum for scientists and researchers to meet, network, learn, and rest with complimentary breakfast at 7AM, refreshments at noon and afternoon receptions.

Featured lectures include:

- Setting Up a Lab
- Mentorship: A Key to Success
- NIH Grants/Working With Industry
- ATS Foundation Grants

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ATS Conference *(Continued from page 7)*

Outside Organization Session for Veterans Health Administration Research & Development Program:

MILLION VETERAN PROGRAM: OPPORTUNITIES FOR STUDY OF GENETIC CONTRIBUTIONS TO RESPIRATORY DISEASES

Monday, May 20, 2019, 12:15 PM – 1:15 PM

Speakers: Muralidhar S, VA MVP Director; Wan ES, Zimolzak A

VA Interest Group Meeting

Sunday, May 19, 11:45 AM – 1:15 PM

Open meeting for ATS members who work in the VA system or are interested in working in the system.

Lunch will be served!

RSVP to bportelli@thoracic.org



Let's discover together.

ATS
2019
Where today's science
meets tomorrow's care™

INTERNATIONAL CONFERENCE
May 17- May 22, 2019
Dallas, Texas

Quarterly Spotlight Series on NIH Institute Intramural Divisions – NHLBI

The NHLBI's Division of Intramural Research (DIR), comprises 12 different branches and centers that conduct scientific and clinical research on the basic elements of molecular, cellular, and organ-level biology and their relationship to disease.

Since 2013, Robert Balaban, who holds a PhD in physiology and pharmacology, has headed the division. Prior to moving to NHLBI, Dr. Balaban was chief of the National Institutes of Health's Laboratory of Cardiac Energetics.

The DIR encompasses the following branches and centers, which relate to pulmonary, critical care, and sleep health:

Pulmonary Branch

The Pulmonary Branch, headed by Kenneth Olivier, MD, MPH, formerly with the National Institute of Allergy and Infectious Diseases Clinical Infectious Diseases Lab, conducts research ranging from molecular and cell-based investigation to bedside and population-based research. The branch also provides

clinical pulmonary physiologic testing, consultative and advanced bronchoscopic services, and offers specialty research training of pulmonary and critical care clinical fellows.

The branch houses the Asthma and Inflammation, Chronic Airway Infection, and Translational Research laboratories. The Asthma and Lung Inflammation Lab, headed by Stewart Levine, MD, focuses on developing new treatment approaches for severe asthma. The lab is working on advancing the

Quarterly Spotlight Series *(Continued from page 8)*

concept of an inhaled apoA-I mimetic peptide for the treatment of asthma from mouse models into the first human clinical trials.

Chronic Airway Infection

The Laboratory of Chronic Airway Infection, headed by Kenneth Olivier, MD, MPH, is studying bronchiectasis and associated infections, including nontuberculous mycobacteria. Specifically, the lab's scientists are examining common genetic characteristics of people with these conditions to determine how such infections lead to disease, with the aim of developing more effective treatments. Additionally, the lab is researching genetic diseases, such as cystic fibrosis, primary ciliary dyskinesia, and heritable connective tissue disorders, including Marfan syndrome, and immune-related disorders associated with bronchiectasis.

Translational Research

The Laboratory of Translational Research, run by Joel Moss, MD, PhD, conducts primary clinical and translational research studying the pathogenesis and treatment of cystic lung diseases, such as lymphangioleiomyomatosis.

Biochemistry and Biophysics

This division is spearheading innovative work in lung imaging. Marcus Chen, MD, and Adrienne Campbell, MD, who will be awarded the ATS Research Innovation and

Translation Award at ATS 2019, are leading investigators in this work.

Immunology Center

The Immunology Center conducts research into the molecular basis of immune processes that apply to a variety of diseases, including genetic immunodeficiencies, cancers, autoimmune diseases, and allergic diseases. Researchers study function, signaling processes, gene regulation, and epigenetics related to the activation and function of immune cells.

Systems Biology Center

The Systems Biology Center develops and evaluates integrated models of biological processes to study gene and protein expression, enzyme activity and other biological processes in a spatial and temporal context. Researchers are interested in diverse systems, including cardiac disease, oxidative stress, cellular differentiation and memory, cell energetics, and metabolism.

Population Science Branch

The Population Sciences Branch synthesizes past advances and future trends related to heart, lung, blood, and sleep disorders, utilizing the thousands of participants in the Framingham Heart Study and other population cohorts. The branch amalgamates traditional epidemiology and longitudinal studies with state-of-the-art genetic and -omics technologies to study

and identify molecular signatures of disease phenotypes in population settings.

Sickle Cell Branch

The NHLBI's DIR also houses the sickle cell branch, which in December 2018 reported promising, early findings from a human clinical trial testing a novel gene replacement therapy in people with severe sickle cell disease. Preliminary results indicate that the therapy is safe and has the potential to help patients produce normal red blood cells instead of the characteristic sickle-shaped ones.

In addition to the above branches, the NHLBI DIR houses these branches and centers:

- Cardiovascular Branch
- Hematology Branch
- Cell and Developmental Biology Center
- Translational Vascular Medicine Branch ■

ATS Conference (Continued from page 9)

DOD RESEARCH OPPORTUNITIES

DOD Medical Research Grant Opportunities Now Open

Funding announcements for several Dept. of Defense Peer Reviewed Medical Research Program (PRMRP) recently opened. Several program announcements are listed below. Fiscal year 2019 PRMRP topic areas include: acute lung injury, burn pit exposure, respiratory health, sleep disorders, pulmonary fibrosis, and tuberculosis. View the full list of applicable health conditions and additional information about the PRMRP here. ■

CDMRP PRMRP Discovery Award *Department of Defense, Dept. of the Army – USAMRAA*

The aim of the PRMRP Discovery Award is to support innovative, non-incremental, high-risk/potentially high-reward research that will provide new insights, paradigms, technologies, or applications. Studies supported by this award are expected to pave the way for future directions of scientific investigation. The proposed research project should include a well-formulated, testable hypothesis based on a sound scientific rationale and study design. The anticipated direct costs budgeted for the entire period of performance for an FY19 PRMRP Discovery Award are not more than \$200,000. The DOD will support up to 50 Discovery awards. The

application deadline is April 11, 2019, and the funding opportunity number is W81XWH-19-PRMRP-DA. ■

CDMRP Peer Reviewed Medical Research Program Investigator-Initiated Research Award

Department of Defense, Dept. of the Army -- USAMRAA

The PRMRP Investigator-Initiated Research Award (IIRA) aims to support up to 16 awards for studies that will make an important contribution toward research and/or patient care for a disease or condition related to at least one of the FY19 PRMRP topic areas.

The rationale for a research idea may be derived from a laboratory discovery, population-based studies, a clinician's first-hand knowledge of patients, or anecdotal data. Applications must include relevant data, which may be published or unpublished, that support the rationale for the proposed study. The IIRA supports research with the potential to generate highly impactful data that could lead to important discoveries or major advancements.

The funding opportunity number is W81XWH-19-PRMRP-TTDA.

The application deadline is July 11, 2019. ■

CDMRP Peer Reviewed Medical Research Program Technology/Therapeutic Development Award

Department of Defense, Dept. of the Army – USAMRAA

The PRMRP Technology/Therapeutic Development Award (TTDA) is a product-driven award mechanism intended to provide support for the translation of promising preclinical findings into products for clinical applications, including prevention, detection, diagnosis, treatment, or quality of life, in at least one of the congressionally directed FY19 PRMRP topic areas. Products in development should be responsive to the health care needs of military service members, Veterans, and/or beneficiaries. The DOD will fund up to 16 awards. The application deadline is July 11, 2019, and the funding opportunity number is W81XWH-19-PRMRP-TTDA. ■

CDMRP Peer Reviewed Medical Research Program Clinical Trial Award

Department of Defense, Dept. of the Army -- USAMRAA

The PRMRP Clinical Trial Award supports the rapid implementation of clinical trials with the potential to have a significant impact on a disease or condition addressed in at least one of the congressionally directed FY19 PRMRP topic areas. Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs or biologics), devices, clinical guidance, and/or emerging approaches and

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technologies. Proposed projects may range from small proof-of-concept trials (e.g., pilot, first in human, Phase 0), to demonstrate feasibility or inform the design of more advanced trials, through large-scale trials to determine efficacy in relevant patient populations. The DOD will fund nine awards. The application deadline is July 2, 2019, and the funding opportunity number is W81XWH-19-PRMRP-CTA. ■

CDMRP Peer Reviewed Medical Research Program Focused Program Award

Department of Defense, Dept. of the Army – USAMRAA

The PRMRP Focused Program Award mechanism is intended to optimize research and accelerate solutions to a critical question related to at least one of the congressionally directed FY19

PRMRP topic areas through a synergistic, multidisciplinary research program. The anticipated direct costs budgeted for the entire period of performance for an FY19 PRMRP Focused Program Award will not exceed \$7.2M. The application deadline is July 2, 2019, and the funding opportunity number is W81XWH-19-PRMRP-FPA. The DOD will fund up to four of these awards. ■

RESEARCH POLICY NEWS

ATS Supports Fetal Tissue Research As Anti-Abortion Groups Call for NIH Director's Ousting

In September 2018, the Department of Health and Human Services ordered a suspension of federally sponsored intramural human fetal tissue research and stated that it would be conducting a review of this research. The suspension of fetal tissue research has thus far affected three intramural studies at National Institute of Allergy and Infectious Diseases, the National Eye Institute, and the National Cancer Institute. The first study, being conducted by NIAID's Rocky Mountain Research Labs in Montana, was set to be the first animal trial testing a new theory about HIV progression but has been put on hold. The suspension is also affecting one extramural HIV study at the University of California, San Francisco, whose funding has been extended for only 90 days, rather than a year.

In late fall 2018, HHS hosted a series of listening sessions with scientific organizations and academic institutions that support fetal tissue research and groups opposed to

fetal tissue research. In December 2018, the ATS joined other groups led by the International Society for Stem Cell Research in co-signing a letter of support for federally sponsored fetal tissue research. The letter, sent to the House Oversight and Government Reform Committee and the other to the HHS Secretary Alex Azar, enumerated the past advances, including treatments for cystic fibrosis, and potential future benefits of this research.

The letter states that, although alternative research models such as induced pluripotent stem cells and organoids may reduce the need for fetal tissue to address some research questions, they cannot replace it. The letter also states, "Decades of thoughtful deliberation on the conduct of fetal tissue research has provided an ethical and policy framework for valuable ethical research to progress, leading to the discovery of new treatments. Additional restrictions on this lifesaving research would be disruptive to biomedical research and devastating to patients."

At an NIH Advisory meeting on Dec. 13, 2018, NIH Director Francis Collins, MD, PhD, stated that fetal tissue research will continue to be a "mainstay" of medical investigations. Dr. Collins also told reporters that the HHS review was intended to "assure the skeptics" of the scientific benefits of this research. Following his comments, some anti-abortion groups have called for Dr. Collins's resignation as NIH Director. Dr. Collins has enjoyed strong bipartisan support in Congress so his forced resignation is unlikely. ■

Rare Diseases/Patient Advocacy

RARE DISEASES

NIH Rare Disease Day –
February 28, 2019



On February 28, 2019, NIH will host its annual event to raise awareness about rare diseases, the people they affect, and current research collaborations. Sponsored by National Center for Advancing Translational Sciences and the NIH Clinical Center, Rare Disease Day at NIH will take place from 8:30 a.m. to 4 p.m. in the Natcher Conference Center on the NIH main campus in Bethesda, Maryland. The event is free and open to the public and will feature presentations on collective research models for rare diseases and patient registries and exhibits and tours of the NIH Clinical Center. This year will also include the presentation of the first ever Zebbie award for the NCATS Rare Diseases Are Not Rare! Challenge.

On Feb. 22, NIH will host a Twitter chat on rare diseases from 1 to 2 p.m. ET. The chat will feature NIH Director Francis S. Collins, MD, PhD, and NCATS Director Christopher P. Austin, MD, as well as representatives from the rare diseases advocacy community. Join in the conversation via #NIHChat. View the Rare Disease Day agenda [here](#) and register for the event [here](#). ■

PATIENT ADVOCACY

Asthma Advocacy - When
Patients, Providers, &
Policymakers Collaborate

By **Tonya A. Winders**, President & CEO, Allergy & Asthma Network, ATS PAR Member

“The whole is greater than the sum of the parts.” This Aristotle quote is certainly true when we consider how the asthma community has joined forces to advocate for patients and achieve great things together.

Beginning in 2004, patients and physicians advocated for students’ right to carry emergency asthma medications at school, and all 50 states now have laws protecting this right. In the last several years, we have also advocated successfully for increased NIH and NHLBI funding for asthma research. We have focused on environmental policy and tobacco policy to ensure that the air we breathe is clean. Finally, the asthma advocacy community is now advocating for emergency albuterol to be stocked in schools for those who may not have their own prescription on hand when an exacerbation occurs. Thus far, 13 states have adopted this measure, and five more are likely to do so.

Our community also advocates against policies that could harm asthma patients. For example, in November 2018 we joined forces to fight the approval of Primatene Mist as an over-the-counter medicine. The ATS, Allergy & Asthma Network, and others are continuing this effort today by imploring pharmacy chains to hold this potentially harmful product behind the counter and educate asthma patients on guidelines-based care. We have also come together to address issues like step therapy and out-of-pocket maximums for patients to ensure access to treatment is not controlled by insurance payers.

Every year advocacy events like the ATS Hill Day in March and the annual Allergy Asthma Day on Capitol Hill in May, tactics like email blasts, phone calls and letter-

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writing campaigns to decision makers, give us a chance to have our voices heard. We still have many policy issues to address and hope you will join us at one of the 2019 events or respond to our call to contact local, state, and federal officials on important advocacy issues. ■

WASHINGTON UPDATE

Health Research Funding Update

Fiscal year (FY) 2019 funding for all government agencies including the FDA, the EPA, and the departments of State and Homeland Security has not been finalized as we go to press, but Congress is moving forward on FY2020. The release of the President's proposed budget usually kicks off the process during the first week of February, but the budget release has been delayed due to the government shutdown and lack of progress on finalizing FY2019. At this point, we expect the President's proposed FY2020 preliminary budget to be released on March 11, 2019, with all program-level numbers released the following week of March 18.

A particular challenge to health research and service agencies, including the NIH and CDC, which fall under a category known as "non-defense discretionary spending (NDD)," is the return of NDD spending caps, enacted under the Budget Control Act of 2011. Unless Congress and the President negotiate a new broad budget agreement these funding reductions will kick in.

The NDD budget caps would necessitate funding reductions of about 9 percent across all NDD spending, including the NIH and CDC. We expect that the President's proposed FY2020 budget will align with the NDD spending caps, which will mean significant proposed funding reductions for NIH, CDC, and other health agencies.

However, it is important to note that the President's budget is a guideline for Congress to consider. Final agency and program funding levels for FY2020 will be proposed first by House appropriations committees in the spring 2019, to be followed by proposals from the Senate. We expect that Congress will be able to negotiate some type of budget deal with the President that would prevent the NDD caps from being triggered.

The NIH has broad bipartisan support in both the House and the Senate so we expect that the agency will likely see at least a minor funding increase, even if the President's budget proposes a funding cut. With Democrats in charge of the House of Representatives, the CDC may also receive a boost in funding FY2020.

Throughout the FY2020 spending process, it will be important for ATS members to educate their members of Congress about the need to continue to increase biomedical research and public health funding in order for the NIH and the CDC to continue making scientific advances to improve detection, treatment, and prevention of respiratory diseases, critical illnesses, and sleep disorders. ■