

## THE AD HOC GROUP FOR MEDICAL RESEARCH

## Ad Hoc Group Weekly Round Up

September 14, 2020

Each week, the Ad Hoc Group Weekly Round Up will feature hashtags and/or tweets (follow us at <a href="mailto:@fundNIH">@fundNIH</a>) suggested by members of the National Institutes of Health (NIH) advocacy community. We encourage all readers who are active on social media to use these messages, and we welcome suggestions from the community for future issues of the Weekly Round Up. Here is this week's featured tweet:

#### Research!America @ResearchAmerica - September 14

<u>#CeliacDiseaseAwarenessDay</u> calls to light the 3 million Americans who currently live with this condition. It takes 6-10 years on average to be correctly diagnosed. <u>#Research</u> into treatments for <u>#Celiac</u> helps enhance quality of life. Read more: https://bit.ly/33lv25R

#### Update on CR, Senate Fails to Advance COVID-19 Supplemental

House Majority Leader Steny Hoyer (D-Md.) would like the House to vote on a continuing resolution (CR) the week of September 21, in advance of the end of the fiscal year on September 30, according to a September 14 interview conducted by <u>CQ Roll Call</u> (subscription required). The updated timeline follows an agreement between Speaker Nancy Pelosi (D-Calif.) and Treasury Secretary Steve Mnuchin earlier in the month that the CR would be considered separately from emergency supplemental spending for COVID-19.

The Senate failed to advance COVID-19 relief legislation after a 52-47 procedural vote on September 10. The \$500 billion Delivering Immediate Relief to America's Families, Schools and Small Businesses Act (S.178), introduced by Senate Republicans, was deemed a "skinny" package in comparison to the more comprehensive Heroes Act (H.R. 6800) passed by the House on May 15. The legislation did not contain proposed funds for the NIH. Following the Senate's failed procedural vote, it is unclear if Congress can reach an agreement on another COVID-19 emergency supplemental package before the end of the fiscal year (see BGOV, subscription required).

#### **NIH Director Testifies Before Senate HELP Committee**

NIH Director Francis Collins, MD, PhD, testified about the importance of vaccinations before the Senate Health, Education, Labor, and Pensions (HELP) Committee on September 9 in a hearing titled, "Vaccines: Saving Lives, Ensuring Confidence, and Protecting Public Health." In his testimony, Dr. Collins reviewed the efforts of Operation Warp Speed in developing a COVID-19 vaccine, as well as the role of the ACTIV and RADx initiatives in investigating new therapeutics and diagnostics for COVID-19. Dr. Collins testified that "rigorous clinical testing required to establish vaccine safety and

efficacy means that it may take some time for a licensed SARS-CoV-2 vaccine to be available to the general public, but there is growing optimism that one or more of these vaccine candidates will prove safe and effective by late 2020 or early 2021."

#### Senate Science Committee to Mark Up RISE Act

The Senate Committee on Commerce, Science, and Transportation will mark up <u>S. 4286</u>, the Research Investment to Spark the Economy (RISE) Act during a <u>September 16</u> <u>Executive Session</u> beginning at 9:45 am EST. The bill would authorize \$10 billion to NIH to support COVID-19 research or research disrupted by the pandemic, out of a total of \$26 billion authorized to federal research agencies.

# ACTIV Launches Clinical Trials of Blood-Clotting Treatments for COVID19

The NIH, as part of the ACTIV initiative, has launched three Phase 3 trials to evaluate the use of blood thinners to treat blood clotting associated with COVID-19 according to a <a href="September 10 news release">September 10 news release</a>. The ACTIV-4 Antithrombitics trials will be conducted globally on COVID-19 patients who have not been hospitalized, who are currently in the hospital, and those discharged from the hospital. "There is currently no standard of care for anticoagulation in hospitalized COVID-19 patients, and there is a desperate need for clinical evidence to guide practice," said NIH Director Francis Collins, MD, PhD. "Conducting trials using multiple existing networks of research sites provides the scale and speed that will get us answers faster," he added.

#### NIH Council of Councils Holds September Meeting

The NIH Council of Councils convened on September 11, including an update on NIH's COVID-19 response from NIH Director Francis Collins, MD, PhD. Dr. Collins summarized emergency supplemental funds for NIH, the ACTIV, RADx, Operation Warp Speed, and serology initiatives, and NIH's communications with the White House Coronavirus Task Force, Congress, and the media. Other presentations touched on artificial intelligence, nutrition for precision health, and more.

#### **NIH Policy for Charging PPE to Grants**

The NIH issued a grants quide notice on September 11 to provide guidance on regulations for charging the costs of personal protective equipment (PPE) used in combatting the coronavirus to NIH grants. According to the notice, "PPE purchased with grant funds must directly assist in safely carrying out the clinical activities and direct interactions with the patients participating in clinical trials and clinical research studies. Therefore, the costs are allowable for researchers and patients directly linked to the clinical studies."

# Upcoming Events

# AIRI to Hold 2020 Annual Meeting, Present Fauci with 2020 Public Service Award

The Association of Independent Research Institutes (<u>AIRI</u>) 2020 Annual Meeting will be held virtually on September 14-16 with an exciting lineup of general session speakers, including <u>AIRI Public Service Award recipient</u>, Dr. Anthony Fauci. AIRI was pleased to recognize Dr. Fauci with the Association's highest honor this past April for his unwavering

commitment to biomedical research and his leadership during the coronavirus pandemic. The Annual Meeting will also feature a keynote presentation from Ms. Esther Krofah, the Executive Director of FasterCures at the Milken Institute, who will discuss the biomedical innovation ecosystem and reflect on lessons learned from the COVID-19 pandemic. Please register for the annual meeting here.

#### Virtual Rally for Medical Research - September 16-17

The Rally for Medical Research is held every September and includes more than 350 national organizations coming together in support of to call on our nation's policymakers to make funding for National Institutes of Health (NIH) a national priority and raise awareness about the importance of continued investment in medical research that leads to more progress, more hope, and more lives saved. This year's event will be held virtually on September 16-17. For more information and to register for the virtual reception, please visit rallyformedicalresearch.org.

#### Global Liver Institute's Advanced Advocacy Academy – October 26-30

The Global Liver Institute's fourth annual Advanced Advocacy Academy (A3) will take place worldwide on October 26-30. This year's virtual event will offer liver patients, caregivers, and professionals the opportunity to learn from experts in the fields of drug development, clinical trials, state and federal legislation, media and communications, and liver health and disease. Live discussions with faculty members will enhance individual learning, foster engagement, and promote important conversations. Self-paced lessons can be customized to fit each attendee's personal learning style and schedule. Anyone impacted by liver disease and passionate about liver advocacy should apply for A3 2020 online by October 1. For more information, see the attached flyer or contact a3@globalliver.org.

#### Virtual NIH Regional Seminar – October 27-30

The NIH is hosting a <u>virtual regional seminar</u> on program funding and grants administration from October 27-30. The event website includes a <u>detailed agenda</u> with keynote speakers and concurrent sessions. <u>Registration</u> is free and available on the event website.

# Requests for Public Comment

#### NLM Seeks Feedback on 10 Year Strategic Plan - October 19

The National Library of Medicine (NLM) issued a request for information (RFI) to solicit public comments and assist NLM in its efforts to implement the NLM Strategic Plan 2017-2027. Specifically, NLM seeks feedback "on major opportunities or challenges relevant to the NLM mission that have arisen or become more important in the last five years and that have implications for the future of NLM in its capacity both as an institution conducting and supporting research and as a national library providing biomedical information products, services, training, capacity-building, and other resources to the world." Comments are due no later than October 19 via webform .

# **OLAW Seeks Feedback on Semiannual Animal Inspections – October 22** The NIH Office of Laboratory Animal Welfare (<u>OLAW</u>) is seeking stakeholder input on flexibilities available for conducting semiannual animal facility inspections. Specifically,

OLAW seeks input on flexibilities available to Institutional Animal Care and Use Committees for conducting semiannual inspections of their animal facilities. Additional details are provided in the <u>request for information</u>. Comments must be <u>submitted</u> <u>electronically by October 22</u>.

#### NINDS Seeks Feedback on Strategic Planning Process

The National Institute of Neurological Disorders and Stroke (NINDS) published a <u>July 2019 request for information</u> on the institute's strategic planning process. The goal of the process is to tune its practices and policies to its vision and mission, in order to better serve and anticipate the needs of the research and patient communities and the public. The mission of NINDS is to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease. Those interested in submitting comments for consideration as NINDS establishes a new strategic plan may still do so <u>through this form</u>.

### NIH COVID-19 Resources

NIH COVID-19 resource for applicants and grantees including guidance for various aspects of research and grant application processes, as well as FAQs and COVID-19 funding opportunities.

<u>COVID-19 "Updates History" webpage</u> that details relevant updates for applicants and grantees by date.

**FAQ document on COVID-19 flexibilities** related to policies and programs affecting the grants process.

<u>Funding opportunities specific to COVID-19</u> lists active and expired funding opportunities across NIH related to SARS-CoV-2/COVID-19 research.

<u>HHS COVID-19 awards tracking website</u> including data on awards made by all HHS awarding agencies with supplemental appropriations.

# Job Postings

#### ASM Seeks a Regulatory Affairs Specialist

The American Society for Microbiology (ASM)'s Policy and Advocacy Department seeks an experienced Regulatory Affairs Specialist to strengthen its presence with federal agencies, specifically CMS and FDA, and proactively identify opportunities for ASM federal policy engagement on clinical and regulatory matters. This person will monitor, analyze, and report on regulatory activity that has the potential to affect the microbial sciences and clinical microbiology community in assigned policy areas, and work with ASM members and staff to develop position statements, testimony, and regulatory comments. View the full job description and <a href="mailto:apply-here">apply here</a>. For more information about ASM, go to: <a href="https://www.asm.org">www.asm.org</a>

**Please Note:** If you have information of interest to the NIH advocacy community that you would like to share with the Ad Hoc Group, please forward it to Christa Wagner at <a href="mailto:chwagner@aamc.org">chwagner@aamc.org</a> or Tannaz Rasouli at <a href="mailto:trasouli@aamc.org">trasouli@aamc.org</a>.