

# THE AD HOC GROUP FOR MEDICAL RESEARCH

### Ad Hoc Group Weekly COVID-19 Follow Up

September 24, 2020

In this time of the COVID-19 pandemic, we will be publishing an additional weekly update focused on COVID-19 to highlight related NIH actions and guidance as well as activities from the Ad Hoc Group community and general updates. As always, please forward any relevant items to Christa Wagner (<u>chwagner@aamc.org</u>) for inclusion in the publication!

# Congressional and NIH News

### House Passes CR Through December 11 House Working Through CR Negotiation, Rules Committee Scheduled to Meet

The House of Representatives passed a continuing resolution (CR) to extend government funding through December 11 by a vote of <u>359-57</u> on September 22. The Senate is expected to begin floor consideration of the Continuing Appropriations Act, 2021 and Other Extensions Act (<u>H.R. 8337</u>, section by section is <u>here</u>) today. The CR as passed by the House does not include additional funds for NIH but does include language allowing NIH to provide no cost extensions to specific grants available for obligation through FY 2015 and set to expire on September 30, 2020 (Sec. 152).

### Candidates for Top House Appropriations Democrat Vow to Bring Back Earmarks

<u>A September 22 report in CQ Roll Call</u> reports that two of the three candidates to replace Rep. Nita Lowey (D-N.Y.) as the top Democrat on the House Appropriations Committee are in favor of bringing back earmarks, an opportunity to label appropriated dollars for specific projects. According to the report, "Marcy Kaptur of Ohio and Debbie Wasserman Schultz of Florida have each committed to bringing back earmarks if chosen as the Appropriations Committee's top Democrat after the November elections. A third candidate, Rosa DeLauro of Connecticut, didn't embrace that stance but didn't rule it out, saying it was 'premature' to discuss restoring earmarks at this stage."

### NIAID Director to Testifies on Federal COVID-19 Response

National Institute of Allergy and Infectious Diseases (NIAID) Director <u>Anthony Fauci, MD,</u> <u>testified</u> on September 23 before the Senate Health, Education, Labor, and Pensions Committee on the federal response to COVID-19 along with two other federal health officials. The hearing focused on updates regarding COVID-19 vaccine development through Operation Warp Speed and availability of new COVID-19 tests. This hearing was likely the final hearing for Chairman Lamar Alexander (R-Tenn.) before his retirement at the end of the 116th Congress.

### NIH Expands Clinical Trials to Test Convalescent Plasma Against COVID-19

<u>A September 22 NIH news release</u> announced an expansion of ongoing clinical trials testing convalescent plasma to treat COVID-19 in hospitalized patients. These studies using blood plasma from patients who have recovered from COVID-19 to treat severely ill patients were launched in the spring with funding from Operation Warp Speed. "We need to carry out rigorous randomized control clinical trials to determine how this therapy can improve outcomes," said NIH Director Francis S. Collins, M.D., Ph.D. "While the world waits for an effective vaccine, it is vital that we simultaneously expand the options for available treatments for those currently suffering from the worst effects of this disease."

### Fourth Large-scale COVID-19 Vaccine Trial Begins in the United States

<u>A September 23 NIH news release</u> reported the start of a fourth Phase 3 COVID-19 vaccine clinical trial, to investigate the safety and efficacy of a single dose vaccine. The trail, funded in part by the National Institute of Allergy and Infectious Diseases, will enroll 60,000 participants across over 200 research sites around the world. "This is an unprecedented feat for the scientific community made possible by decades of progress in vaccine technology and a coordinated, strategic approach across government, industry and academia," said NIAID Director Anthony Fauci, MD, commenting on the swift eightmonth timeline from virus identification to Phase 3 testing. "It is likely that multiple COVID-19 vaccine regimens will be required to meet the global need," Fauci added.

# Upcoming Events

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

The Global Liver Institute's fourth annual <u>Advanced Advocacy Academy (A3)</u> 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 <u>apply for A3 2020</u> <u>online</u> by October 1. For more information, see the attached flyer or contact <u>a3@globalliver.org</u>.

#### 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.

### NExTRAC Meeting – November 9-10

On November 9-10, 2020, NIH will be hosting a virtual meeting of the Novel and Exceptional Technology and Research Advisory Committee (<u>NExTRAC</u>). The NExTRAC provides recommendations to the NIH Director and serves as a public forum for the discussion of the scientific, safety, and ethical issues associated with emerging

biotechnologies. More information about the meeting will be posted, as it becomes available, to the <u>NExTRAC page</u> of the <u>OSP Website</u>.

## Ad Hoc Group Member Resources

#### **Research!America Vote Science Strong Campaign**

Research!America recently launched a national campaign-engagement initiative, <u>Vote</u> <u>Science Strong</u>, aiming to elevate the importance of research and innovation in the national conversation this election season. The campaign includes resources for voters and candidates to learn and engage on the importance of funding medical research and the impacts of research on human disease.

# NIH COVID-19 Resources

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

**<u>COVID-19</u>** "Updates History" webpage 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.

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

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

## **Job Postings**

#### Epilepsy Foundation Seeks to Fill Positions on Its Research Team

**Senior Director, Innovation, Research & New Therapies,** whose primary responsibilities include: directing the Epilepsy Foundation's Innovation and Entrepreneurship programs, working with the CMIO in setting the objectives and key results for the Research & New Therapies (R&NT) staff and assists in budget preparations and quarterly monitoring for the R&NT team and providing supervisory and mentoring support to R&NT staff, as needed. <u>Click here to see the full job posting and apply</u>.

**Research Program Manager,** whose primary responsibilities include: Coordinating the development and delivery of the Epilepsy Digital Engagement Navigator (EDEN); developing engagement strategies, and work with our platform partner to ensure data is entered in the platform in an interpretable manner under the direction of the Director of Innovation and the CMIO; working with research clinical coordinator in the Human

Epilepsy Project 2 study; assisting with analysis of research data sets by pulling and analyze various query requests from research data sets existing within the Foundation; and maintaining the web informational research tools such as the pipeline tracker. <u>Click here to see the full job posting and apply</u>.

#### 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 <u>apply here</u>. For more information about ASM, go to: <u>asm.org</u>

**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 <u>chwagner@aamc.org</u> or Tannaz Rasouli at <u>trasouli@aamc.org</u>.