From: Croft, Genevieve
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CoR NEWS
(10-16-15)

To: APLU Council on Research
From: APLU Staff

- **Common Rule Proposed Revisions: APLU-AAU Working Group Update, and Upcoming Town Halls**
- **APLU Submits Comments to the FDA on Changes to the International Regulation of Ketamine**
- **Federal Effort to Modernize the Regulatory System for Biotechnology Products**
- **NSF issues revised Proposal & Award Policies & Procedures Guide**

- Common Rule Proposed Revisions: APLU-AAU Working Group Update, and Upcoming Town Halls

The APLU-AAU working group on response to proposed changes to the Common Rule is up and running. Joint comments are anticipated to be submitted to OHRP by the December 7 deadline.

Both the Office of Human Research Protections (OHRP) and the NIH CTSA Coordinating Center will host several upcoming town hall and discussion sessions on the Common Rule NPRM. Each event may be attended in-person or via webinar. Details and registration information are below.

OHRP public town hall on the Common Rule NPRM *(The webcast may be watched live on October 20, beginning at 9 am (EDT) here. Additional information is available here.)*

October 20, 2015
Washington, D.C.
9 am - 5 pm EDT

Four regional sessions on discrete NPRM topics, hosted by the NIH CTSA Coordinating Center *(Invite and registration information here; and meeting-by-meeting details here.)*

Requiring Consent for Research with Biospecimens and Allowing Broad Consent

October 14, 2015
Nashville, Tennessee
10 am- 3 pm CT
Vanderbilt University Student Life Center

Streamlining IRB review
October 29, 2015
San Diego, California
9:00 am - 2:00 pm PT
San Diego Convention Center

Revising and expanding the scope of the Common Rule
November 5, 2015
Chicago, Illinois
9:00 am - 2:00 pm CT
Hilton Orrington/Evanston

Enhancing and clarifying consent forms and establishing standard safeguards
November 18, 2015
Philadelphia, Pennsylvania
10:00 am - 3:00 pm ET
Sheraton Philadelphia University City Hotel

- **APLU Submits Comments to the FDA on Changes to the International Regulation of Ketamine**

This week APLU submitted a letter to the Food and Drug Administration (FDA) expressing concern with potential changes to the international regulation of ketamine, a drug used by biomedical researchers, including to sedate and provide analgesia for animals in their care.

APLU notes that the proposed restrictions on access to ketamine could result in increased difficulty for researchers to use the drug for legitimate and appropriate treatments, ultimately hindering many forms of federally-funded biomedical research in the U.S.

- **Federal Effort to Modernize the Regulatory System for Biotechnology Products**

On July 2, 2015, the Executive Office of the President (EOP) issued a memorandum directing the primary agencies that regulate the products of biotechnology—the U.S. Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA)—to (1) update the Coordinated Framework for the Regulation of Biotechnology (CF), (2) develop a long-term strategy to ensure that the Federal biotechnology regulatory system is

prepared for the future products of biotechnology, and (3) commission an expert analysis of the future landscape of biotechnology products to support this effort.

On October 6, 2015, the National Science and Technology Council released a Request for Information (RFI) to solicit relevant data and information, including case studies, to inform this effort. In addition to this RFI, the CF update will undergo public comment before it is finalized. We encourage your institution to respond to this RFI with relevant data for consideration.

This week, the FDA, along with the Office of Science and Technology Policy, the EPA, and the USDA, announced a public meeting to inform the public about the activities described in the July 2015 memorandum, invite oral comments from interested parties, and provide information about how to submit written comments, data, or other information to the docket. This meeting will be held on **October 30 at FDA in Silver Spring, MD.** An archived webcast will be made available after the meeting. Additional information about this public meeting, including how to submit questions, can be found here.

- **NSF issues revised Proposal & Award Policies & Procedures Guide**

The National Science Foundation (NSF) has issued a revised *Proposal & Award Policies & Procedures Guide* (PAPPG), (NSF 16-1). This new guide will be effective for **proposals submitted, or due, on or after January 25, 2016**. As highlighted by NSF, significant changes include:

- Enforcement of 5 p.m. submitter's local time across all NSF funding opportunities;
- Implementation of NSF's Public Access Policy;
- Submission of proposal certifications by the Authorized Organizational Representative (AOR) concurrently with proposal submission;
- NSF's implementation of the US Government Policy for Institutional Oversight of Life Sciences on Dual Use Research of Concern;
- Provision of Collaborators and Other Affiliations information as a new single-copy document, instead of as part of the Biographical Sketch;
- Submission of Biographical Sketches and Current and Pending Support separately for each senior personnel;
- Electronic signature and submission of notifications and requests by the AOR only;
- Revision of timeframe for submission of final project reports, project outcomes reports and financial closure of awards to 120 days after the award end date; and
- Numerous clarifications throughout the document.

NSF will host a webinar explaining the new guide on **October 29th at 2 PM EST**. Registration is required, here.

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