

UC Office of the President

U.S. Department of Health and Human Services (HHS)

Title

UC Request to FDA to Extend Comment Period for Docket No. FDA-2021-N-0286 for
“Protection of Human Subjects and Institutional Review Boards” (September 28, 2022)

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<https://escholarship.org/uc/item/8z99q8c0>

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OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

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Sent via <https://www.regulations.gov/commenton/FDA-2021-N-0286-0001>

October 27, 2022

Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
North Bethesda, MD 20852

RE: Docket No. FDA-2021-N-0286 for “Protection of Human Subjects and Institutional Review Boards” (September 28, 2022)

Dear Dr. Califf:

I write on behalf of the University of California (UC) system in regards to the Notice of Proposed Rulemaking (NPRM) titled “Protection of Human Subjects and Institutional Review Boards” published in the Federal Register on September 28, 2022.

The UC system is comprised of ten research-intensive campuses, six medical schools, and three affiliated U.S. Department of Energy national laboratories. As a system, UC receives approximately \$7 billion annually of extramural awards to support research conducted throughout all UC locations, with nearly half of the funds supported through federal funding.¹

We appreciate the work that the Food and Drug Administration (FDA) undertook to harmonize its human subject protection regulations with the Federal Policy for the Protection of Human Subjects (Common Rule). UC is striving to provide the FDA with specific feedback, however 60-day comment period is inadequate to thoroughly assess the intricacies of the proposed changes. In order to compose thoughtful comments, we will need to consult with faculty members, administrators, and investigators involved in research, compliance, and privacy throughout the UC system. The investigators and academic institutions directly affected by the proposed changes deserve a reasonable and fair opportunity to evaluate how the NPRM will impact human subject research protections and oversight. Therefore, the UC system respectfully requests an additional 60-day extension to the original 60-day comment period, for a total of 120-day comment period.

¹ University of California Accountability Report 2022:
<https://accountability.universityofcalifornia.edu/2022/chapters/chapter-9.html>

If you have any questions concerning these comments, please contact Agnes Balla, Research Policy Manager, at agnes.balla@ucop.edu.

Sincerely,

A handwritten signature in black ink, appearing to read 'DM Motton', with a long horizontal flourish extending to the right.

Deborah Motton, Ph.D.
Executive Director
Research Policy Analysis and Coordination
University of California, Office of the President