

# **UC Office of the President**

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

## **Title**

UC Letter Regarding Gender Diversity and Inclusion on the OHRP IRB Registration Form

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OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

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Sent via email to [jerry.menikoff@hhs.gov](mailto:jerry.menikoff@hhs.gov)

December 9, 2021

Jerry A. Menikoff, M.D., J.D.  
Director, Office for Human Research Protections  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852

**RE: Gender Diversity and Inclusion on the OHRP IRB Registration Form**

Dear Dr. Menikoff:

I write on behalf of the University of California (UC) system to ask you to consider a practical change on the Office for Human Research Protections (OHRP) [IRB Registration Form](#) that would allow for a more inclusive representation of those serving on the Institutional Review Board (IRB).

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 \$6 billion annually of extramural awards to support research conducted throughout all UC locations, and generally receives five to six percent of the NIH annual appropriations for research.<sup>1</sup>

In November 2020, UC implemented the [Gender Recognition and Lived Name Policy](#) that allows students, faculty, employees and affiliates to acknowledge their preferred gender identities and lived names on all UC documents and information systems. The policy requires that UC provide at least three gender options, such as male, female and nonbinary, on all UC-issued documents and forms. UC's policy follows other recent efforts aimed at building inclusion, including the [2017 California Recognition Act](#) that made it easier for those who are transgender and nonbinary to legally identify themselves on documents according to their choosing. We respectfully ask that the OHRP take a similar step by acknowledging that IRB members may identify themselves by their preferred gender on the IRB Roster component of the IRB Registration Form.

Specifically, [§46.107\(a\)](#) requires that each IRB have diversity in its membership, including in gender. Moreover, the OHRP in its [FAQs](#) notes that an IRB must “make every nondiscriminatory effort to ensure that the membership is not composed of entirely men or entirely women.” Based on the regulatory requirements, HHS and other federal agencies that have adopted the Common Rule

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<sup>1</sup> University of California Accountability Report 2021:  
<https://accountability.universityofcalifornia.edu/2021/chapters/chapter-9.html>

place emphasis on ensuring diversity in membership as opposed to an evenly composed board of male and female members. However, the OHRP's IRB Registration Form does not reflect the same spirit of nondiscriminatory effort emphasized in the regulations and even the FAQ information since the form only lists two gender options, male or female. We urge the OHRP to revise this form and acknowledge at least three gender identity options on the form, if not more. For example, the OHRP may amend the form to ask for gender identity, as opposed to "sex M/F", and provide the following options: man, woman, nonbinary, or different identity.

As the OHRP well knows, the IRB is charged with upholding national and community standards as it pertains to research participant protections, but they are also charged with promoting diversity and inclusion within research. If the OHRP and other federal agencies want to convey a message of diversity and inclusion in research, we must apply the same standard to our IRBs, including by allowing IRB members to select their gender identity more broadly than currently available.

Thank you for your consideration on this important issue. If there is further information UC can provide on this matter that would be of assistance to the OHRP, we would be delighted to help.

Sincerely,

A handwritten signature in black ink, appearing to read "Deborah Motton", with a stylized, flowing script.

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

A handwritten signature in blue ink, appearing to read "Elizabeth Halimah", with a stylized, flowing script.

Elizabeth Halimah  
Associate Vice Provost and Chief Policy Officer  
Graduate, Undergraduate and Equity Affairs  
University of California, Office of the President