



School of Medicine
Division of Biomedical Sciences
Riverside, CA, 92521

April 24, 2020

To: Dylan Rodriquez, Ph.D., Chair, Academic Senate, UCR Division

From: Declan McCole, Ph.D., Chair, Faculty Executive Committee, UCR School of Medicine

Subject: SOM FEC Response to Proposed Policy: Presidential Policy on Protection of Human
Subjects in Research

Dear Dylan,

The School of Medicine Faculty Executive Committee discussed the Proposed Policy: Presidential Policy on Protection of Human Subjects in Research today. The committee has 4 concerns relating to Page 4; Section IV (Compliance/Responsibilities); Campus responsibilities, paragraph 2, which states: Research in which the University is engaged that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution.

- Given that human subjects research at UCR is hampered by often lengthy negotiations and approvals by outside IRBs (i.e. partner hospitals/clinics each of which have their own IRBs) it is important to clarify which UCR officials have this veto power over IRB approvals as this can have long term consequences for research partnerships with local hospitals.
- What qualifications do these officials need to have in order to properly evaluate and potentially veto an IRB approval?
- Under what conditions would IRB approval be over-ruled by said officials?
- What is the time line for this over-ruling action by a UCR official?

Yours sincerely,

A handwritten signature in black ink that reads "Declan McCole".

Declan F. McCole, Ph.D.
Chair, Faculty Executive Committee
School of Medicine