

From: **Jack Hu** <[jackhu@umich.edu](mailto:jackhu@umich.edu)>  
Date: Mon, Jan 30, 2017 at 3:24 PM  
Subject: Important Notice from Dr. S. Jack Hu - Institutional Official for Human Subjects Research  
To: Research Associate Deans Faculty <[radfaculty@umich.edu](mailto:radfaculty@umich.edu)>

On January 19 2017, the U.S. Department of Health and Human Services and 15 other federal departments and agencies published a Final Rule (82 Fed. Reg. 7149) to revise the [Federal Policy for the Protection of Human Subjects](#) (the Common Rule). This revision is the first reform to the Common Rule since 1991 and generally has an implementation date of January 19, 2018. In response to comments they had received, the agencies did not finalize many of the most controversial and burdensome changes to the Common Rule that had been proposed in the earlier Notice of Proposed Rulemaking. We believe that some of the changes will actually reduce administrative burden for investigators and the IRBs. While we are eager to implement these beneficial changes, because of the timing of the release of the Final Rule, it could be nullified under the provisions of the Congressional Review Act (“CRA”).

U-M’s IRBs are working with national organizations to understand the changes described in the more than 120 pages of the Final Rule. Assuming the new regulations stand, we will revise U-M’s human research policies, operationalize them in the eResearch system and IRB procedures, and put them into effect when allowed and/or required under the new rules.

Until then, our current U-M IRB policies and processes remain in effect — all human research conducted by U-M employees and students must obtain approval or an exemption determination prior to beginning research. Our [Human Research Protection Program website](#) provides links to U-M policies and procedures for human subjects research.

A Department of Health and Human Services press release summarizing the new rule can be found here: <https://www.hhs.gov/about/news/2017/01/18/final-rule-enhances-protections-research-participants-modernizes-oversight-system.html>.

Questions about the Final Rule and U-M’s policies may be directed to: [hrppumich@umich.edu](mailto:hrppumich@umich.edu)

Sincerely,

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