June 23, 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)](https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects) on January 18, 2017 to revise the Federal Policy for the Protection of Human Subjects (the [Common Rule](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/)). This revision is the first reform to the Common Rule since 1991 and has a planned implementation date of January 19, 2018. An overall summary of the changes to the Rule, courtesy of the Council on Governmental Relations (COGR), is found [here](http://www.cogr.edu/sites/default/files/Summary%20of%20Changes%20to%20the%20Common%20Rule_COGR.pdf).

However, the federal government placed a ‘freeze’ on new and pending regulations at the beginning of the new presidential administration by issuing a 60-day hold on rules that have been published in the Federal Register; the effective date yet to be determined. When (or if) the status of the Common Rule effective date changes, the campus community will be updated on how these changes will affect research at UMBC.

There have been no significant changes to the Common Rule in many years. These new rules are intended to strengthen human use subjects protections. Some of the changes that may affect our campus include:

* Changes to the consent form process that provides subjects with a better understanding of the research.
* Requirement for a single IRB review for multisite studies.
* The establishment of new exempt categories of research based on the level of risk.
* Removal of the requirement to conduct continuing review of ongoing research studies in certain instances where such review does little to protect subjects.

The Office of Research Protections and Compliance (ORPC) is closely following the status of the revisions to the Common Rule and hope to hear updates soon. We will inform our campus constituents and stakeholders once we have more definitive information with regard to status. The ORPC is also beginning to review current policies and practices with regard to any changes we may need to implement to meet the revision to the Final Rule. Until then, please stay tuned for updates on the ORPC’s [Institutional Review Board website](http://research.umbc.edu/institutional-review-board-human-subjects/). Also, feel free to contact us at [compliance@umbc.edu](mailto:compliance@umbc.edu) if you have any further questions or concerns.