Dear Colleagues,

As many you will have heard, the long-anticipated revision to the Federal Policy for the Protection of Human Subjects, known as the Common Rule, was published in the Federal Register January 19, 2017, with implementation of most provisions scheduled for January 19, 2018. The Trump administration's reconsideration of regulations adopted in the last months of the Obama administration has created considerable uncertainty regarding whether the revisions would be implemented.

At this point, most opportunities for revocation have passed. The Final Rule currently is under review by the administration, with no indication as to when the review will be completed. However, the director of the Office for Human Research Protections has stated publicly that he does not anticipate there will be any changes to the regulations, except perhaps a delay in implementation, as requested by numerous stakeholders. We are preparing policies and procedures for the University to reflect the changes, whether they take effect in January 2018 as published or after.

The Revised Rule may lessen certain administrative constraints on conducting some low-risk human research studies. We support reduction of the regulatory burdens for our investigators and administration, however, our first obligation remains to protect human subjects. Convenience and efficiency should not compromise this obligation.

Recently, there have been articles published with expanded interpretations of the Revised Rule. For example, the Revised Rule does not specify who determines whether certain lower-risk studies must undergo IRB review. Some have interpreted the silence as a license to conduct research without submission to the IRB for review and approval - a self-regulation of research. Conversely, the Revised Rule does not suggest that someone other than the researcher make the determinations, and leaves the process for this determination to the institution.

Please keep in mind that, as of right now, the regulations governing human subjects research remain unchanged. If and when the Revised Rule takes effect, we will modify the IRB review and approval process appropriately and communicate those changes to you. For examples, there may be changes in exempt submission forms, informed consent documents, and continuing review requirements for some studies. Many of these changes will streamline the IRB review and approval process.
As always, the federal rules set a baseline for oversight and the institution determines the appropriate policies and procedures to protect the rights and welfare of those who participate in the research. We are committed to upholding those protections at Georgia State University.

Best regards,

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Vice President for Research and Economic Development